

#### **Profile**

Einancial Highlighte

Chugai Pharmaceutical aims to transform itself into a company that creates value globally. To this end, the Company has focused on strengthening its prescription pharmaceutical business —its core business activity, establishing a position as a leading company in biotechnology, and enhancing its business platform to engage in the pharmaceutical business on a global scale.

In pursuit of these aims, Chugai Pharmaceutical signed an agreement in December 2001 to enter into a strategic alliance with F. Hoffmann-La Roche Ltd. Following shareholders' approval in June 2002, Chugai Pharmaceutical merged with Nippon Roche K.K. in October 2002 and made a fresh start as "new Chugai." Shortly beforehand, the Company's shares in Gen-Probe Incorporated were distributed to Chugai Pharmaceutical shareholders and Chugai Diagnostics Science Co., Ltd. was sold, completing the Company's withdrawal from the non-core diagnostics business.

In addition, the Company withdrew from the agrichemical and medical device businesses in fiscal years ended March 2002 and 2003 respectively, in order to increase focus on the Company's selected business areas and reallocate management resources.

Through these measures the Company has further strengthened management resources in its core business and has enhanced its global business platform.

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#### **Forward-Looking Statements**

This annual report includes forward-looking statements pertaining to the business and prospects of the Company. These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company's businesses.



### **Financial Highlights**

Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries Nine months ended December 31, 2003, Years ended March 31, 2003, 2002

		A (Except as other	Millions of yen wise specified)	Thousands of U.S. dollars (Note) (Except as otherwise specified)
	2003/12	2003/3	2002/3	2003/12
For the year:				
Net sales	¥ 232,748	¥ 237,391	¥ 211,705	\$ 2,175,215
Prescription pharmaceuticals	218,157	217,476	165,139	2,038,850
Nonprescription products	14,590	19,914	22,877	136,355
Operating income	42,719	30,317	26,709	399,243
Net income (loss)	28,446	(20,135)	14,598	265,850
Research and development expenses	43,525	48,511	47,845	406,776
At year-end:				
Total assets	¥ 405,197	¥ 425,301	¥ 349,226	\$ 3,786,888
Total shareholders' equity	296,717	277,254	200,779	2,773,056
Interest-bearing debts	10,761	12,108	70,093	100,570
Amounts per share (Yen, U.S. dollars):				
Net income (loss) -basic	¥ 51.73	¥ (51.75)	¥ 57.93	\$ 0.48
Net income (loss) -fully diluted-	50.94	_	49.09	0.48
Cash dividends	13.00	16.00	16.00	0.12
Shareholders' equity	542.96	503.41	796.67	5.07
Number of outstanding shares	550,691,219	550,633,518	252,068,564	
Ratios:				
Operating income to net sales (%)	18.4	12.8	12.6	
ROE (%)*	9.9	(8.5)	7.5	
Total shareholders' equity to total assets (%)	73.2	65.2	57.5	
Debt-to-equity ratio (%)	3.6	4.4	34.9	•
Interest coverage ratio (Times)**	79.4	78.7	53.0	
Research and development expenses to net sales (%)	18.7	20.4	22.6	
Number of employees	5,680	5,774	4,964	

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Note: The U.S. dollar amounts have been translated from Japanese yen at the rate of ¥107 to US\$1.00, the exchange rate prevailing on December 31, 2003. Figures are not fully comparable due to the merger with Nippon Roche, the spin-off of Gen-Probe and the sale of Chugai Diagnostics Science in the fiscal year ended March 2003, as well as the change in fiscal year-end in the year ended December 2003.

\* ROE=Net income/Total shareholders' equity (yearly average) × 100

<sup>\*\*</sup>Interest coverage ratio=(Operating income+Interest and dividend income)/Interest expenses



# Dear Shareholders and Investors

Over a year has now passed since Chugai became a member of the Roche Group, and in that time we have seen our relationship of trust with Roche go from strength to strength, and the smooth shift to a new system following our merger with Nippon Roche.

Accompanying this, we are now beginning to see the benefits of the alliance. With the pharmaceutical industry currently going through some drastic changes, we must constantly be on the lookout for new approaches. As the new Chugai, our goal is "to become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines domestically and internationally." With this goal in mind, we will redouble our efforts to build the most appropriate operating system while making maximum use of the alliance.

## Chugai's Future Direction within the Pharmaceutical Industry Facing Tougher Challenges

The environment surrounding pharmaceutical companies is now undergoing profound changes, including revisions to the medical care system, a shift to borderless markets, and scientific and technological innovations.

In April 2004, the government imposed revisions to the reimbursement of medical fees. This resulted in an average 4.2% reduction in drug prices for the industry as a whole. In the domestic market, growth is leveling off as the rise in demand from the aging population is offset by policies to suppress medical expenses through repeated drug price reductions and by the more extensive coverage of the prospective flat-sum payment system. As you can see, the environment in which we operate continues to present constant challenges. Globalization is one means of ensuring growth in the midst of such an environment and is becoming more important.

In addition, due to the dramatic progress being made in life-science following the completion of the human genome code sequencing, there is now fierce global competition among companies to develop drugs with new mechanisms, as well as medications for illnesses for which, up until now, there has been no effective treatment. As a result,

we are now faced with globally elevating costs in research and development requiring us to achieve greater efficiency in all areas: R&D, marketing, production, and distribution to ensure continued growth.

As CEO, the greatest task I face is mapping out a sound growth strategy for the Company by building the most appropriate operating system whilst ascertaining the direction in which changes are occurring to the medical system.

#### The Alliance

The decision to form a strategic alliance with F. Hoffmann-La Roche Ltd. (Roche) was also made with this in mind and represents a most important development in Chugai's history. Although our global development was temporarily delayed, through the unprecedented alliance with Roche, we have paved the way for global development to advance in the fields in which we excel, and this includes biopharmaceuticals. Roche is the forerunner in a wide variety of bio-related fields ranging from R&D platforms in genomics to production technology for biopharmaceutical products. Genentech in the U.S., and a member of the Roche Group, is one of the world's leading companies in the development of biopharmaceutical products. When Chugai, one of the top Japanese biopharmaceutical companies, joined the Roche Group, a tripartite cooperative system was forged between Japan, the U.S., and Europe for the future development and production of large molecule biotechnology compounds, including antibody drugs now possible through post-genome drug discovery.

## Looking back on the Period Ended December 2003 (April 1, 2003 – December 31, 2003)

Due to the change in fiscal year-end, the fiscal year ended December 2003 was for the nine-month period from April to December 2003, and we were able to post sales in line with our plan, at 232.7 billion yen. On the operating income side, the ratio of cost of sales to net sales rose from the greater percentage of Roche products that were included in our sales, and license fee payments were posted to research and development expenses as a result of in-licensing two Roche compounds. However, the reorganization of plants and laboratories, ongoing since the merger with Nippon Roche, progressed according to plan, and in addition, large-scale reductions were made in our overall expenses. As a result, we managed to achieve an operating income of 42.7 billion yen, with the operating income margin showing significant improvement, rising from 12.8% to 18.4%.

A 3.3 billion yen milestone revenue based on our licensing contract with Roche for the joint development and sales promotion of the antibody drug, MRA, was posted as other income, and, as a result, our net income for the fiscal year under review reached 28.4 billion yen. We decided to pay a dividend of 13 yen per share, which is 17.33 yen per share when calculated on a yearly basis and exceeds the level of the previous fiscal year of 16 yen per share.

If we analyze sales by business, sales of prescription pharmaceuticals, which accounted for 93.7% of total sales, amounted to 218.2 billion yen; a figure above expectation. There were some products, however, for which sales fell short of the plan as the start of a 30% co-payment rate for medical insurance, effective as of April, saw fewer people undergoing medical examinations. Nevertheless, Epogin®, an agent for the treatment of

anemia associated with end-stage renal disease, reported brisk sales and the anti-tumor drugs Rituxan® and Herceptin® saw strong growth. Two new products also contributed to sales: Xeloda® for the treatment of breast cancer and Renagel®, the hyperphosphatemia treatment, both of which were launched in June 2003.

On the other hand, looking at nonprescription products (over-the-counter, "OTC", drugs), although sales of Guronsan® brands (nutritional supplement drinks) were good, sales of the household insecticide Varsan® fell markedly due to the cool summer and as a result, sales of OTC drugs amounted to only 14.6 billion yen. While this business continues to struggle amid a harsh environment, through the closure and divestiture of nutritional supplement drink plants conducted in the fiscal years ended March and December 2003, the outsourcing of the drink manufacturing, and the transfer of about 90 personnel out of 280 at our healthcare company to the other divisions, we believe we have successfully established the foundation for maintaining a stable profit from now on.

Looking to changes to our balance sheets, total assets declined by 4.7% compared with the end of the previous fiscal year, owing to the payment of income taxes payable related to the spin-off of Gen-Probe Incorporated. On the other hand, liabilities were reduced by 26.5% as a result of the repayment of debt. Consequently, our shareholders' equity ratio rose from 65.2% to 73.2%.

In addition, we repurchased 4,300,000 shares of our own stock (of this, 231,000 shares worth of stock options were given to directors and key employees.) I am confident that this stock repurchase will result in higher value for shareholders by improving supply-and-demand for stock with a reduction in the number of outstanding shares and increasing motivation of our directors and employees.

As for our relationship with the Roche Group, we have been deepening our mutual understanding and strengthening our cooperative system through the regular meetings of six joint committees, including the Management Committee. During the fiscal year under review, there were a number of events that made us feel that the alliance is having an effect; specifically, the start of the global joint development of the antibody drug MRA, research collaboration related to small molecular synthetic compounds, technological cooperation related to the production facilities for antibody drugs, and the introduction from Roche of two antibody drugs in the field of oncology (R435 and R1273).

#### Chugai's Envisioned Future

#### Chugai's Mission Statement (excerpt)

#### Mission

Chugai's mission is to dedicate itself to adding exceptional value through the creation of innovative medical products and services for the benefit of the medical community and human health around the world.

#### **Envisioned Future**

As a most important member of the Roche Group, we aim to become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines domestically and internationally.

At the time of our merger with Nippon Roche in October 2002, we drew up our mission statement as the new Chugai, in which we stated our ideas for an "envisioned future," "As a

most important member of the Roche Group, we aim to become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines domestically and internationally."

By maximizing the resources of the Roche Group network, we aim to globally develop innovative new medicines, and simultaneously help position the group as one of the top in the world in the field of biopharmaceuticals, the area in which it now excels. At the same time, we will promote alliances with venture businesses and academia on a global basis.

Here in Japan, in order to enhance our market presence as a top pharmaceutical company, we are focusing on achieving a growth rate that greatly exceeds that of the market through the continuous launch of promising new medicines. In the fiscal year ended December 2003, Chugai launched three new products and ranked fourth in terms of sales on the Japanese market for prescription pharmaceuticals. We currently have 22 compounds in our development pipeline, a number which parallels that of other top Japanese pharmaceutical companies. We also have seven applications (including indication expansions) waiting for approval, and expect a continuous flow of new drugs to be introduced both from our own research efforts and Roche's pipeline.

#### Issues Currently Facing Chugai

In order to realize our "envisioned future," we set three targets for the fiscal year ending December 2005 as shown below. For the time being, it will be 'full steam ahead' here at Chugai to achieve these targets.

#### Targets for the fiscal year ending December 2005:

- (1) Sales of 315 billion yen, and an operating income margin of 20%
- (2) Gain the leading position in the fields of oncology, renal diseases, and bone and joint diseases
- (3) Early realization of the win-win relationship with the Roche Group (Ensure the success of Roche's products in Japan through Chugai, and establish the foundations for global development of Chugai's products using Roche's business infrastructure)

To achieve these targets, we intend to focus on (a) the promotion of growth of existing products and the assurance of the early market penetration of new products (Xeloda® for oncology, Renagel® for renal disease area, and Pegasys® for the treatment of chronic hepatitis C, all of which were marketed in the fiscal year ended December 2003, and for bone and joint diseases, Evista™, a treatment for post-menopausal osteoporosis that is scheduled to be launched in May 2004), (b) the implementation of further cost reductions and rationalization, and (c) the acceleration of global development and sales promotion of MRA.

MRA is attracting a lot of attention as the first antibody drug originated in Japan. It is also the first joint development project between Chugai and Roche, and we are strongly committed to accelerating its global development. Its expected indication is for rheumatoid arthritis and other immune system abnormalities as well as inflammatory diseases, such as Castleman's disease and juvenile idiopathic arthritis. It is said that there are an estimated 4–5 million rheumatoid arthritis patients in Japan, Europe and the U.S., and we intend to position MRA as an important strategic product that will add momentum to our drive towards globalization.

#### Further Strengthening of Our Management System

On October 1, 2003, we revamped our organization in order to complete the introduction of the new system and promote efficiency in management. Previously, our organization featured a CEO Office that acted between the CEO and divisional headquarters. However, with the organizational revision, the CEO Office was abolished and the following three control headquarters—Research & Development Group, Technology & Production Group, and Sales & Marketing Group—were set in place to serve as coordinators between top management and related divisions; a decision which I think has now resulted in speedier and more efficient decision-making. In addition, in order to increase motivation among our management teams, this fiscal year Chugai provided stock options to internal directors and key employees. We are also investigating the possibility of expanding the stock option system to include regular employees in the future.

To strengthen our corporate governance and compliance activities, an independent auditing team was newly inaugurated in the fiscal year under review with the specialized role of providing support to the audit function for all-round improved corporate governance. We also combined our Corporate Ethics Department with the Environmental Affairs Section of the General Affairs Department to form the Corporate Social Responsibility Promotion Department to raise the level of compliance from the perspective of Corporate Social Responsibility (CSR). From now on, we will continue to work to further strengthen our system with the aim of ensuring efficient and highly transparent management that is expected of a global company.

In closing, I wish to thank all of Chugai's shareholders and investors for your understanding and cooperation during fiscal year ended December 2003, in light of the many changes that occurred within the Company with the shift to the new system, such as the fiscal year irregularly being nine months.

The fiscal year ending December 2004 will be our first full year as the new Chugai. Although we anticipate a tough business environment, we will do our utmost to produce results that will be satisfactory to every one of you, and hope that Chugai's management can count on your continued understanding and support.

March 2004

Osamu Nagayama

Chairman, President and CEO

Chugai aims to establish a long-term 'win-win' relationship with Roche by contributing to promote and increase the value of the Roche Group yet also maintain most of its own unique characteristics through autonomous management. Chugai's most important contribution will be the marketing of new drugs in Japan that are introduced by Roche whilst also supplying the world with new drugs of its own creation and raising its own corporate value.

The foundations for realizing this 'win-win' relationship are already in place. Through the alliance, Chugai has established a research and development base with superior international competitiveness. Moreover, through employing targeted financial strategies, it has been able to expand its capital, stabilize its earnings base, and significantly reduce business risk. In marketing, in addition to maintaining the right to independently develop its overseas business, Chugai will be able to make use of the Roche Group network based on discussions with Roche as needed.

On the other hand, the Roche Group has also benefited through this alliance, greatly strengthening its business base in Japan, the second largest pharmaceutical market in the world. In 2003, Roche's prescription medicines sales in Japan accounted for 16% of its overall sales; this is up from 6% in 2001. The new Chugai is ranked fourth in terms of sales of pharmaceutical products on the Japanese market (in the fiscal year ended December 2003) and holds a 4.1% share.

#### Points of Agreement in the Alliance with Roche:

#### 1. Capital

Chugai merges with Nippon Roche, forming the "new" Chugai. Roche becomes Chugai's majority shareholder (50.1%).

#### 2. Business

Chugai has first refusal rights to develop and market Roche products in Japan.

In cases where Chugai determines that it needs a partner, Roche has first refusal rights to develop and market Chugai products outside of Japan and South Korea.

#### 3. Management

Roche guarantees that Chugai maintains management autonomy (including all functions of research, development, production, and marketing) and its stock remains listed in Japan.

#### Outline of Roche

Company name:

Roche Holding Ltd. (Basel, Switzerland)

Chairman and CEO:

Dr. Franz B. Humer

Sales:

29 Bil. Swiss francs (FY2003)

(Continuing business basis)

R&D expenditure:

4.7 Bil. Swiss francs (FY2003)

Main business:

Pharmaceuticals (74%), diagnostics (26%)

R&D focus on seven therapeutic area:

Oncology, metabolic disorders, virology,

cardiovascular diseases, urology,

central nervous system, and inflammatory diseases

Top-selling products:

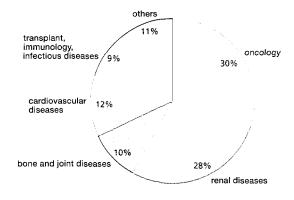
MabThera/Rituxan, NeoRecormon,

Rocephin, CellCept, Herceptin, Pegasys · Copegus, Xeloda

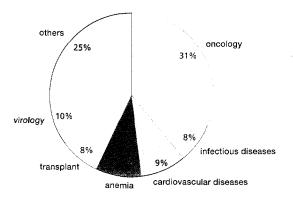
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 Chugai and Roche, a Comparison of Strategic Therapeutic Fields (Prescription medicines 2003-Percentage of net sales)

#### Chugai



#### Roche



#### O Chugai and Roche, R&D Platforms



- Biopharmaceuticals
- Antibody technology
- Transgenic technology
- Vitamin D derivatives
- Protein production



- Genomic research
- Informatics
- Biopharmaceuticals
- Therapeutic antibodies
- Protein production

#### Collaboration



- Information and technology exchange
- Efficient resource usage
- Cooperation in protein production
- Collaboration in target identification and biopharmaceutical development projects

To realize the relationship, it is necessary to maximize synergies with Roche and in those areas where the two companies are able to complement each other.

Research & Development In addition to being two companies dedicated to R&D, Roche and Chugai share the common goal of making active use of biotechnology, and in terms of research resources and platforms, there are many areas in which they can hope to achieve synergies and complement each other's strengths. Some synergies are already being realized through the joint global development of MRA, the companies' first joint project, and collaboration in research related to small molecular synthetic compounds.

*Marketing* Chugai's five strategic fields of oncology, renal diseases, bone and joint diseases, cardiovascular diseases, and transplant, immunology and infectious diseases largely match those of Roche (see chart), therefore, Chugai can expect synergies concerning complementary products within the same field or in related fields.

**Production & Technology** In the area of antibody drugs in particular, where development is likely to accelerate, there is concern about a global shortage of production facilities sometime in the future. However, as huge capital is required to construct the facilities, and as technology is rapidly advancing, it is difficult to predict the direction for investment.

At present, Chugai is in the midst of constructing Japan's largest antibody production facilities. By combining these with those presently owned by Roche and Genentech, we can form a global tripartite relationship, with the group possessing one of the world's top production capacities. Chugai intends to continue responding to the ever changing market needs and work in close collaboration with its partners.

### Progress Being Made with Synergies from the Alliance

Up to now, Chugai has been working towards realizing synergies in three areas: Sales, Cost, and Research and Development. As a result, some synergies are gradually now being generated.

## 1. Sales Synergy (Improvements to Sales Productivity)

As the product line-up expanded with the merger with Nippon Roche, Chugai's position further strengthened in the field of bone and joint diseases, as well as in the field of renal diseases, in which it has been number one in Japan, both in terms of sales and market share. In the field of oncology it rose from the number nine to the number two rank (as of December 2003), and maintained competitiveness in Chugai's strategic fields. Moreover, synergies are expanding within fields—for example, in oncology there are more combinations of anti-tumor drugs and supportive cancer treatments\*—and Chugai is now able to cover a broader range of patient needs.

\* Supportive cancer treatments are compounds that prevent and/or control the emergence of side effects from chemotherapy and improve the patient's quality of life.

Chugai has 1,400 Medical Representatives (MRs), which is on a par with the number of MRs of other top-ranked pharmaceutical companies within Japan. At the time of the merger, the company adopted a hybrid marketing system, combining the area marketing system, which

operates by region, with the marketing system based on specialization in particular therapeutic fields. The 80 or so MRs who specialize in particular therapeutic fields are called "Sci-Ver MRs" (or scientific verifying MRs), and are assigned to one of Chugai's five strategic fields. As well as responding to demand for sophisticated specialization in detailing, they have the invaluable role of linking clinical and academic practices, presenting researchers with scientific data to support 'evidence-based medicine' (EBM) and providing feedback to medical practitioners.

A year after the merger, the new system is in full swing, and Chugai is committed to achieving further improvement in productivity.

#### 2. Cost Synergy

The planned reorganization of facilities that began at the time of the merger with Nippon Roche was completed in December 2003. In addition, as a result of adequate hiring and natural attrition, the number of employees on a non-consolidated basis fell from 5,208 (pre-merger total of the two companies) to 4,977 at the new company in December 2003. Moreover, Chugai plans to cut its workforce to 4,700 employees by the year ending December 2005. The selling, general and administrative expense (excluding R&D expenses) ratio has also declined from 34.1% to 27.0% due to increased efficiency.

#### O Cost Synergies

		Pre-Merger			
Re-organization of facilities	Chugai	Nippon Roche	Total	As of Dec. 31, 2003	Dec. 2005 (plan)
Branches	11	13	24	13	
Sub-branches	56	39	95	55	-
Plants	6	1	7	5	
Laboratories	5	1	6	4	
Reduction of headcount					
Headcount (non-consolidated)	3,577	1,631	5,208 (Sep. 2002)	4,977	4,700
Headcount (consolidated)	4,346	1,631	5,977 (Sep. 2002)	5,680	5,290
Reduction of SG&A (R&D exclusive)	34.1%			27.0%	

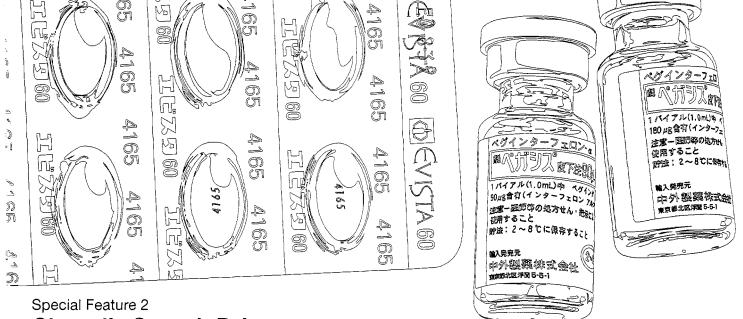
## 3. R&D Synergy (Enhancements to R&D Efficiency and the Development Pipeline)

In order to improve research efficiency, Chugai has agreed to eliminate as much as possible any research overlap with Roche. With this in mind, the joint research committee, formed between Roche and Chugai, meets twice annually, and members exchange information regarding progress made in research as well as proposals related to joint research and opportunities to make use of technology. In the field of biopharmaceuticals, the companies have basically agreed that they will each conduct their own independent research and look for possibilities for collaboration on each project. The two companies exchange information in order to maximize efficiency of the Roche Group.

Moreover, in the field of small molecular synthetic compounds, based on an agreement in October 2002, Chugai and Roche make mutual use of resources such as chemical compound libraries and databases to improve efficiency in development, and to reduce its development risk. In October 2003, Chugai and Roche combined their chemical compound libraries and created one of the richest libraries in the world.

From the development pipeline, expanded as a result of the merger, three new drugs were marketed in the fiscal year ended December 2003

(Renagel®, Xeloda® and Pegasys®. For more details, see p.12-14). As of December 2003, there were 22 new compounds (excluding additional indications) in Chugai's development pipeline, one of the highest numbers among the pharmaceutical companies in Japan. In addition to its own development, Chugai has been continuously expanding its product offerings with those from the Roche pipeline. Following the license contract with Roche concluded in December 2003, Chugai added to its development pipeline two antibody drugs: R435 and R1273 created by Genentech (see p.20).



Chugai's Growth Drivers

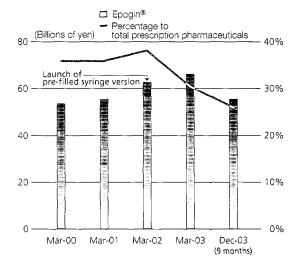
Epogin®, an agent for anemia associated with end-stage renal disease, is one of Chugai's mainstay products, and has been the main growth driver for more than ten years. Although its dominance within Chugai felt the aftereffects from the influx of products with the merger in October 2002, Epogin® is still expected to continue to bolster profitability in the future.

In December 2003, Chugai added three new growth drivers: Renagel®, for the treatment of hyperphosphatemia, Xeloda®, for breast cancer, and Pegasys®, for chronic hepatitis C. Moreover, an additional indication was approved for non-Hodgkin's lymphoma treatment Rituxan®, and sales of this drug are likely to greatly expand. Also, Evista™, for the treatment of osteoporosis in postmenopausal women, is likely to be launched in May 2004. In addition, smooth progress is being made with the development of the antibody drug MRA. In 2003, a new drug application for MRA as an orphan drug was filed for the indication of Castleman's disease, and its evaluation is proceeding as planned.

#### Epogin®: The Growth Driver Up to Now

For the past few years, Epogin® (epoetin beta) continuously accounted for more than 30% of the Company's total prescription pharmaceutical sales. Since it was marketed in 1990, Epogin® has been the Company's main earnings driver. After Chugai joined the Roche Group, the number of its products increased, and as a result, Epogin® sales as a percentage of total prescription pharmaceutical sales fell from 38.0% before the merger (in the year ended March 2002) to 25.5% (in the year ended December 2003). However, sales are currently growing due to an increase in the number of patients and the introduction of a new dosage form with improved convenience (a pre-filled syringe version launched in May 2001), and the Company has high expectations of Epogin®'s future role as a profit driver. At present, there are about 230,000 patients in Japan undergoing kidney dialysis, and are all potential users of Epogin®. This figure is expanding at an annual rate of about 10,000.







Epogin®

#### Further Strengthening its Role as a Growth Driver

The substance patent for Epogin® will expire in 2005. However, it will probably be difficult for generic versions to advance into the market for the time being, owing to the nature of Epogin® as a biopharmaceutical which requires sophisticated manufacturing technology and large capital investment, and the fact that the guidelines on evaluating bio-generics are still unclear. Chugai believes that the strength of the product is attributable to not only its pharmaceutical functions, but also many other factors, such as MRs and their ability to provide information and the Company's full line-up of products in the field of renal diseases. With this in mind, Chugai intends to secure a market share for Epogin® and maximize the Company's presence in the field by further strengthening these factors. At the same time, Chugai aims to elevate the product's value by expanding indications for Epogin® in other fields, such as anemia associated with cancer treatment.

Moreover, Chugai is conducting phase I clinical trials of a second generation anemia product with greater continuity — the continuous erythropoiesis receptor activator (CERA) R744 — a product of Roche origin.

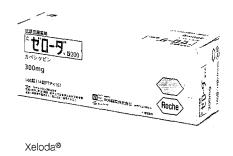


Renagel®

#### Launch of Renagel® in June 2003

In June 2003, Chugai added Renagel®, for the treatment of hyperphosphatemia, to its product line-up in the field of renal diseases. Renagel® (generic name: sevelamer hydrochloride) was introduced from GelTex Pharmaceuticals, Inc. of the U.S. (now, Genzyme Corporation) to Chugai, and is being jointly developed by Chugai and Kirin Brewery Co., Ltd. (The drug is sold under each company's respective brand name.) Approximately 80% of the country's 230,000 dialysis patients have contracted hyperphosphatemia, and of these patients an estimated 25% have probably not seen sufficient improvement with existing drugs. Renagel® is designed to target the treatment of these patients. Chugai and Kirin forecast to post a combined figure of around 12 billion yen (on a National Health Insurance (NHI) drug price basis) during peak sales of sevelamer hydrochloride.

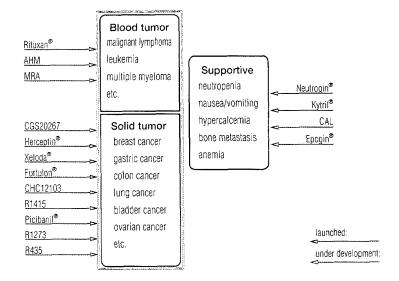
Renagel® is Japan's first non-absorbed calciumand aluminum-free phosphate binder. Normally, about 800-1,200mg of phosphorous is contained in a person's daily meals. Patients with chronic renal insufficiency (i.e., their renal function is decreased) must have this phosphorous removed through dialysis as it cannot be sufficiently eliminated by the kidneys alone. However, this dialysis treatment is not yet able to fully prevent the onset of hyperphosphatemia. Calcium carbonate, the conventional substance used to treat this condition, can induce hypercalcemia, thus sometimes limiting the dosage to an insufficient level. Renagel® inhibits the absorption of phosphates into the body without causing this side effect. In addition, as it is impossible for hypercalcemia to occur with Renagel®, synergies can be expected with the Company's other products: for example, the dosage of vitamin D3 derivatives can be increased. This is especially true for Oxarol®, an agent for the treatment of secondary hyperparathyroidism which is easier to use in combination with Renagel®. In the field of renal diseases, Chugai offers five important products that can be prescribed with the addition of Renagel®, giving the Company the leading domestic product line-up.



## Strengthening Chugai's Position in the Oncology Field

The product line-up that was the most strengthened as a result of Chugai's joining the Roche Group was in the field of oncology. As of March 2003, Chugai sales of oncology products totaled 68.5 billion yen, giving it about a 13% share of the Japanese market for these products; the second largest share in the industry. In this field, the Company's mainstay product up to now has been Neutrogin®, an agent for neutropenia and a supportive cancer treatment. However, as a result of Chugai's merger with Nippon Roche, its line-up of anti-tumor drugs expanded to include Furtulon®, Herceptin®, Rituxan®, and Xeloda®, with Kytril® the 5-HT3 receptor antagonist antinauseant and antiemetic agent being added to the Company's line-up of supportive cancer treatments. As a result, options to combine anti-tumor drugs and supportive cancer treatments have also increased, leading to synergies within the field. In total, the Company now has ten products in the development pipeline, in the areas of both anti-tumor drugs and supportive cancer treatments, including indication expansions.

Among Chugai's existing products, the ones with particularly high growth potential are the antibody drugs Herceptin® (anti-HER2 monoclonal antibody) and Rituxan® (anti-CD20 monoclonal antibody). Herceptin® is a treatment for HER2 over-expressed metastatic breast cancer and Rituxan® is for treating CD20-positive lymphoma. These drugs work by targeting specific molecules (HER2 and CD20), which are involved in the proliferation of cancer cells. They offer a new choice of treatment that has little effect on normal cells. Herceptin® was launched in Japan in June 2001 and Rituxan® in September 2001. Within half a year after their respective launches, both drugs had rapidly come into widespread use. In the year ended December 2003, sales of Herceptin® totaled 6.8 billion yen and sales of Rituxan® reached 8.2 billion yen. In addition, in September 2003, an additional indication was approved for Rituxan® -- aggressive non-Hodgkin's lymphoma—and peak sales are expected to reach 15-20 billion yen (see p.16).



In the field of oncology, in addition to pursuing new treatments, such as target-based agents that seek out pre-detected specific molecules, Chugai is also enhancing development of its conventional chemotherapeutic agents, and in June 2003, the Company launched the anti-tumor drug Xeloda® (generic name: capecitabine, an antimetabolite enzyme-activation-type 5-FU derivative).

#### Xeloda® (Launched in June 2003)

Xeloda®, a treatment for malignant tumors, was created in 1993 by the Kamakura Research Center of former Nippon Roche (now new Chugai's Kamakura Research Laboratories). Since being approved in the United States in 1998, it has been prescribed as a standard treatment for metastatic breast cancer and colorectal cancer in more than 70 countries worldwide (as of December 2003). In Japan, it is approved for the treatment of inoperable or recurrent breast cancer. In addition, Xeloda® is under development for the indications of gastric cancer and colorectal cancer. For the indication of recurrent breast cancer which has already been approved, sales are expected to peak at 5.0 billion yen (on a NHI drug price basis).

During the breast cancer phase II clinical trials, Xeloda® was shown to be most promising with a 20.0% efficacy rate in cases where docetaxel (an anti-cancer taxane drug) proved to be ineffective. However, there was also a high incidence of side effects (92.1%), such as hand-and-foot syndrome. Thus, as a safety precaution, Chugai provides sufficient warnings about possible side effects by distributing guidelines regarding the appropriate use of Xeloda® to physicians and pharmacists and preparing handbooks for patients. The Company is also accumulating evidential data and will clarify Xeloda®'s position among the different chemotherapy options for breast cancer.



Pegasys®

#### Pegasys® (Launched in December 2003)

The new generation peginterferon alfa-2a agent Pegasys, used in the treatment of chronic hepatitis C, was launched in December 2003. Pegasys® was developed by Roche and approval first granted in Switzerland in 2001. Since then, Pegasys has been approved alone or in combination with R964 (ribavirin), an antiviral agent, in more than 90 countries and has achieved a global market share of over 50% at the end of 2003. Its market share in Japan is expected to grow as well. There are an estimated 500,000 people with chronic hepatitis C in Japan. Of these, 30,000 to 40,000 people are treated with interferon drugs each year, creating a target market with 52 billion yen in 2003.

Pegasys® is likely to generate annual sales of about 15-20 billion yen (on a NHI drug price basis) at its peak, assuming that it is approved for use in combination with R964, currently undergoing phase III clinical trials.

Pegasys® was developed by improving on Roferon®-A, the conventional interferon alfa-2a. By covering the interferon with polyethylene glycol (pegylation), it extends the time that the drug remains in the body. Thus, while it was necessary to administer the conventional interferon agent three times a week, Pegasys® need only be given once a week, improving convenience for patients and reducing the side effects. In addition, in clinical trials conducted overseas, it was found that the combination therapy of Pegasys® and R964 dramatically improved the body's ability to eliminate the virus. For patients found to have high viral load of genotype 1b\*, for which interferon is said to be less effective, this drug combination resulted in an impressive 46% sustained virological response rate.

In this market, several products with enhanced efficacy have been launched, and this new generation of interferon drugs is now replacing the old. Chugai intends for Pegasys® to ride the wave and secure a high market share by strengthening its marketing activities.

#### Evista™ (Scheduled for Launch in May 2004)

Evista™ is a selective estrogen receptor modulator (SERM) used in the treatment of post-menopausal osteoporosis. The drug was co-developed with Eli Lilly Japan and received approval in Japan in January 2004. The drug is now approved in more than 70 countries, including in the U.S. and Europe, and is marketed in more than 60 (as of September 2003).

As it is believed that estrogen drugs may increase the risk of breast cancer, vitamin D drugs are currently the main choice of treatment for osteoporosis in Japan. In clinical trials, Evista™, a SERM that only utilizes the bone-building properties of the estrogen hormone, reported no increase in the incidence of breast cancer and was found to be highly effective in preventing bone fractures. There are several million patients in Japan, and Chugai expects peak sales of 15-20 billion yen.

The field of bone and joint diseases is becoming increasingly more important for Chugai. Three other drugs are currently under development for the indication of osteoporosis (including the anti-resorptive bisphosphonate R484, and ED-71, an activated vitamin D derivative) and in the field of rheumatoid arthritis, clinical trials are ongoing for the antibody drug MRA.

#### The Antibody Drug, MRA

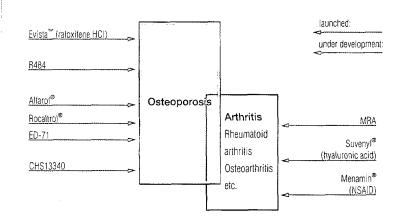
When a foreign substance such as a virus (i.e., antigen) enters a living body, it triggers an immune response in order to remove it. Antibodies play a key role in this process, and when they are developed as pharmaceutical products, these products are called antibody drugs. As antibodies target specific

<sup>\*</sup> Genotype 1b is a genetic classification of the type-C hepatitis virus. Of Japanese patients infected with hepatitis C, 70% are infected with genotype 1b.



antigens, treatments using antibody drugs are expected to be highly effective with fewer side effects. Chugai began research into antibody drugs in 1990. Three years ago, the Company combined its antibody and genomic drug discovery research that uses analyzed genetic information and since then has been conducting unique research in this area entitled "genomic antibody drug discovery." At the same time, it has actively incorporated the necessary technology through collaboration with overseas research institutions. As a result of these efforts, three types of antibody drugs are now at the clinical trial stage: MRA (a humanized anti-human IL-6 receptor monoclonal antibody), CAL (a humanized anti-PTHrP monoclonal antibody), and AHM (a humanized anti-HM1.24 monoclonal antibody). Of these, MRA is the closest to being launched.

MRA is expected to be an effective treatment for rheumatoid arthritis and multiple myeloma, diseases in which cytokine interleukin-6 (IL-6) plays a significant role. In Japan, Chugai has filed a new drug application for MRA for the indication of Castleman's disease, and MRA is already in phase III clinical trials for the indication of rheumatoid arthritis. In Europe, phase II clinical trials for the indication of rheumatoid arthritis have been completed and preparations are being made to commence phase III clinical trials in Europe and the U.S. During the phase II clinical trials in Europe, that involved more than 350 patients, MRA was found to be highly effective in those for whom methotrexate (MTX, the conventional treatment for rheumatoid arthritis) was not entirely successful, either as a monotherapy or



in combination with MTX. There are an estimated 4-5 million sufferers of rheumatoid arthritis in Japan, the U.S. and Europe combined; yet due to the aging population, this number is on the increase.

In July 2003, Chugai concluded a licensing contract with Roche related to the global joint development of MRA and its joint promotion in Europe and the U.S. Currently, preparations for development are underway and a sales promotion system is to be established. Now that the clinical trials for MRA have entered their final stage Chugai is also strengthening its production capacity for antibody drugs. Chugai has two 2,500-liter capacity bioreactors at the Ukima Plant, and two 10,000-liter capacity bioreactors at the Utsunomiya Plant which became operational in January 2004. By 2007, the Company plans to construct more bioreactors in order to bring its total capacity to 85,000 liters in preparation for the commercial supply of the drug.



Antibody production facility (Utsunomiya Plant)

#### **Products Overview**

#### **Prescription Pharmaceuticals**

In the fiscal year ended December 2003, sales of prescription pharmaceuticals totaled 218.2 billion yen. The number of products in our line-up increased significantly from 44 to 73 as a result of the merger with Nippon Roche in October 2002.

#### 1. Japanese Market

Sales of prescription pharmaceuticals in the Japanese market totaled 201.4 billion yen in the fiscal year ended December 2003.

In the field of **oncology**, sales of our mainstay products Rituxan® and Herceptin®, both anti-tumor agents, amounted to 8.2 billion yen (13.9% above original plan) and 6.8 billion yen (19.3% above original plan) respectively. On the other hand, sales of Neutrogin®, an agent for neutropenia and a supportive cancer treatment, was 10.9 billion yen, falling 6.8% short of the original plan. This was partially due to the introduction of the prospective flat-sum payment system for inpatient care in advanced treatment hospitals and a greater choice of treatment methods such as molecular-targeted therapy.

The application for an additional indication for Rituxan® filed by Zenyaku Kogyo Co., Ltd., the license holder of the product in Japan, was approved in September 2003. With this approval, Rituxan®'s indication was expanded to include aggressive grade in addition to the original low-grade non-Hodgkin's lymphoma. Its sales showed significant growth, with a monthly average of 1.47 billion yen during the three-month period from October to December after gaining approval. This represents a doubling of sales from the monthly average of 0.67 billion yen marked during the three-month period from July to September. This indicates that Rituxan® has potential for further growth.

In the field of **renal diseases**, sales of our mainstay product Epogin®, a treatment for anemia associated with end-stage renal disease, grew as expected to 55.7 billion yen, exceeding the planned figure by 0.5%, with the pre-filled syringe version (launched in May 2001) driving the growth. Sales of Oxarol® (injection), an agent for secondary hyperparathyroidism in hemodialysis patients, totaled 4.6 billion yen, indicating that the product has penetrated the market smoothly since its launch in September 2002. Moreover, a hyperphosphatemia treatment Renagel® was launched in June 2003. We expect further growth in demand for these products together with

the increase in number of patients suffering from chronic renal disease, mainly as a complication brought on by diabetes.

In the field of **bone and joint diseases**, sales of osteoporosis agent Alfarol® amounted to 13.5 billion yen, failing to reach the targeted figure due to the increasing burden of medical expenses for the elderly and the influence of the introduction of several new products such as bisphosphonate drugs to the market. However, we expect sales to grow in this field with our plan to launch Evista<sup>TM</sup>, a treatment for osteoporosis in postmenopausal women with a novel mode of action, in May 2004.

In the field of **cardiovascular diseases**, sales of Sigmart®, an anti-angina drug totaled 12.6 billion yen, and sales of Rythmodan®, an antiarrhythmic agent, totaled 6.4 billion yen.

In transplant, immunology and infectious diseases, strong sales of anti-influenza agent Tamiflu® were posted during the previous fiscal year, with sales amounting to 11.6 billion yen. However, due to the unpredictably high incidence of influenza seen in the previous flu season, we experienced problems in supplying a sufficient amount of Tamiflu® to medical institutions. Consequently, for this flu season, we based our production plans on the maximum influenza epidemic observed over the past ten years, preparing enough Tamiflu® to cover ten million patients. In doing so, we believe we have now successfully avoided any repetition of last year's supply shortage.

In this field, in June we launched the injectable bag form of Rocephin®, cephem-type antibiotic ceftreaxone sodium used for the treatment of infectious diseases. This injectable bag form is superior to the conventional dosage form in terms of ease of use, sterility and disposability, and we expect this launch to lead to higher sales. Sales of Rocephin® totaled 3.7 billion yen in the fiscal year under review.

We expect the business environment to remain severe in the fiscal year ending December 2004, due to the industry average 4.2% drug price cut in April, and other measures to contain medical expenses applied by the Japanese government. Despite these adverse conditions, we aim to further expand sales of existing products and ensure smooth market penetration of our four new drugs: Pegasys®, Xeloda®, Renagel® and Evista™ through intensive marketing activities.

#### O Main Products, Prescription Pharmaceuticals (Japanese Market)

Product name (Generic name)	Remarks	Sales (E 2003/3	Billions of yen) 2003/12 (9 months)	
Epogin® (epoetin beta)	Agent for anemia associated with end-stage renal disease	¥ 66.1	¥ 55.7	
Neutrogin® (lenograstim)	Agent for neutropenia associated with chemotherapy	13.7	10.9	
Sigmart® (nicorandil)	Antianginal agent	15,5	12.6	
Alfarol® (alfacalcidol)	Agent for osteoporosis	17.9	13.5	
Furtulon® (doxifluridine)	Antitumor agent	8.1	12.2	
Tamiflu® (oseltamivir)	Anti-influenza agent	12.5	11.6	
Kytril® (granisetron)	5-HT3 receptor antagonist anti-nausea agent	5.1	9.2	
Rituxan® (rituximab)	Anti-CD20 monoclonal antibody, antitumor agent	3.0	8.2	
Herceptin® (trastuzumab)	Anti-HER2 monoclonal antibody, antitumor agent	3.5	6.8	
Rythmodan® (disopyramide)	Antiarrhythmic agent	8.5	6.4	
Suvenyl® (sodium hyaluronate)	Agent for knee pain associated with rheumatoid arthritis	6.0	5.4	
Oxarol® (maxacalcitol)	Agent for secondary hyperparathyroidism in hemodialysis patients	5.2	4.6	
Rocephin® (ceftriaxone)	Cephem-type antibiotic ceftriaxone sodium	2.0	3.7	
Euglucon® (glibenclamide)	Agent for oral hyperglycemic	_	1.8 *	
Renagel® (sevelamer HCI)	Agent for hyperphosphatemia		1.7 **	
Xeloda® (capecitabine)	Antitumor agent		0.9 **	
Pegasys® (peginterferon alfa-2a)	Chronic hepatitis C		0.2 ***	

<sup>\*</sup>Started marketing from October 2003, following the transfer of its sales and marketing rights from Yamanouchi.

#### 2. Overseas Market

Chugai continues to develop overseas markets on its own as in the past. In the fiscal year ended December 2003, sales in overseas markets totaled 16.8 billion yen, which represents 7.2% of our net sales.

We sell two major products on the overseas market: the neutropenia agent lenograstim

(Neutrogin® in Japanese market) and anti-angina agent nicorandil (Sigmart® in Japanese market). Lenograstim is sold through subsidiaries in the U.K., Germany, France and Taiwan and in more than 70 countries around the world through joint ventures. In the fiscal year ended December 2003, lenograstim saw record sales.

#### O Main Products, Prescription Pharmaceuticals (Overseas Markets)

		Sales (	Billions of yen)
Generic name (Product name)	Remarks	2003/3	2003/12 (12 months)
lenograstim (Granocyte®/Neutrogin® in Japanese market)	Agent for neutropenia associated with chemotherapy	¥ 11.4	¥ 13.8
nicorandil (Sigmart® in Japanese market)	Antianginal agent	2.5	1.9

Report Concerning Failure to Perform Early Post-Marketing Phase Vigilance (EPPV) for Immunosuppressive Agent CellCept® (Mycophenolate Mofetil)

In January 2003, CellCept® was approved for additional indications (to counteract rejection of heart, liver and lung transplantations) on the condition that early post-marketing phase vigilance (EPPV) was conducted. However, as we failed to carry out the EPPV, on May 1, 2003, the Ministry of Health, Labour and Welfare requested that the Company report the cause for this failure and its countermeasure. To quickly respond to this incident, we have reviewed the post marketing surveillance management and implementation system of the Post-Marketing Surveillance Management Division and related divisions involved in drug safety. Based on this countermeasure, on May 6, we started EPPV and completed the six-month study. At the same time, we established the Post-Marketing Surveillance Committee and revised standards for operating procedures as well as educational programs to further strengthen the system. We expect these enhancement measures to prevent this kind of failure in the future.

<sup>\*\*</sup>Launched June 2003.

<sup>\*\*\*</sup>Launched December 2003.



Guronsan® and Varsan®

#### Nonprescription Products (OTC products)

Chugai's nonprescription products include Guronsan® and New Guromont® (both nutritional supplement drinks), New Chugai Ichoyaku®, a gastrointestinal medicine, and Varsan®, insecticides for household use. In the fiscal year ended December 2003, sales in this business totaled 14.6 billion yen, as sales of Varsan® saw a larger decline due to the cool summer, despite the steady demand for nutritional supplement drinks.

In the nonprescription pharmaceutical business, we have been introducing a virtual company system since the fiscal year ended March 2001 to establish an independently profitable business. Furthermore, throughout the fiscal years ended March 2003 and December 2003, we either closed or transferred two plants that primarily produce nutritional supplement drinks and switched to outsourcing to reduce fixed costs and improve cost competitiveness. As of the end of December 2003, production of Guronsan® and New Guromont® has been outsourced to Dydo Yakuhin Kogyo Co., Ltd., and Fuji Pharmaceutical Co., Ltd. Moreover, in October we transferred approximately 90 of the total 280 personnel in the Healthcare Company to other divisions of Chugai. With these measures, we have established a platform which can sustain growth in this business.

#### Main Nonprescription Products (OTC Products)

Product name	Remarks		003/12
New Guromont®, Guronsan®	Nutritional supplement drink	(9 · ¥ 8.6	months) ¥ 7.5
Varsan®	Insecticides for household use	6.6	4.0
New Chugai Ichoyaku®	Gastrointestinal medicine	1.6	1.0

### **Development Pipeline**

#### Status of Chugai's Development Pipeline

As of the end of December 2003, Chugai has 22 compounds in its development pipeline excluding additional indications for existing products, an amount that is on a par with other top-class pharmaceutical companies in Japan. By field, there are seven compounds under development in oncology, one in renal diseases, five in bone and joint diseases, two in cardiovascular diseases, one in transplant, immunology and infectious diseases, and six in other fields.

#### Status of Filing and Approval in Japan

In October 2003, the Ministry of Health, Labour and Welfare approved Chugai's application to import Pegasys®, a treatment for chronic hepatitis C, and the drug was subsequently launched on December 12. This was just over one year after filing the application under the fast track review process.

In the fiscal year ended December 2003, Chugai filed applications for two new drugs. In addition to the submission in April for the manufacturing approval of the antibody drug MRA\* for the indication of Castleman's disease, the Company in June applied for an indication expansion for the angina pectoris treatment drug Sigmart® (generic name: nicorandil) to include acute heart failure. As a result, a total of seven drugs that Chugai has developed are now in the filing stage (as of the end of December 2003).

Furthermore, in January 2004, the application for the import of Evista<sup>TM</sup>, a treatment for osteoporosis in postmenopausal women, was approved, and this drug is scheduled to be launched in May 2004. For more details regarding MRA, see also p.14-15.

## Clinical Development Phase for Pre-Application Stage Drugs in Japan

The anti-viral drug R964 (generic name: ribavirin) is expected to be effective when used in conjunction with Pegasys® in the treatment of chronic hepatitis C. Currently, R964 is in phase III of clinical trials.

In the oncology field, phase II clinical trials have finished for Epogin® for the expansion of indications to include the treatment of anemia associated with cancer treatment. Moreover, in October 2003, Chugai began phase II clinical trials for R1415 (generic name: erlotinib) to obtain the indication for

the treatment of lung cancer. Development is also ongoing to extend the indications of the anti-tumor agents Herceptin® and Xeloda®.

In the field of bone and joint diseases, phase II clinical trials have finished for the activated vitamin D derivative ED-71 for the treatment of osteoporosis, and in May 2003, phase II clinical trials began for CHS13340 (a recombinant parathyroid hormone drug, planned indication: treatment of osteoporosis). Moreover, in February 2004, the Company began a phase III double-blind trial with MRA for the treatment of rheumatoid arthritis.

## Boosting the Development Pipeline: Introducing Drugs from Roche

In December 2003, Chugai signed a licensing contract with Roche for the antibody drugs R435 and R1273, which were created by Genentech, and phase I clinical trials are planned to commence in the latter half of 2004. The target indications for R435 and R1273 are metastatic or recurrent colorectal cancer and non-small cell lung cancer, respectively.

#### Overseas Development

In July 2003, Chugai and Roche signed a contract related to the joint development and promotion of MRA, and both companies are now proceeding with the development of the drug in Europe and the U.S. Phase III clinical trials are scheduled to begin in Europe and the U.S. in 2004 for the indication of rheumatoid arthritis. Clinical trials are also underway for indications such as juvenile idiopathic arthritis, systemic lupus erythematodes, and multiple myeloma.

In addition to this, Chugai is conducting clinical development overseas for GM-611, a drug designed to promote the recovery of gastrointestinal motility, as well as for the antioxidant BO-653, and the anti-PTHrP monoclonal antibody CAL through Chugai Pharma U.S.A., LLC (CPUSA), its U.S.-based development subsidiary.

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Development code	Indication / *Additional indication	Area	Status (Filing date)				
			Preparing : for Phase 1 : Phase 1	Phase 2	Phase 3	Filed	: : Approve
Oncology	1	<u>;                                    </u>	Tion Titado T.				
CGS20267	Breast cancer in postmenopausal women	Japan	them Become the article of the April 1991 March 1991 April 1991		I SUN SUR SUMMER	(Jul.00)	:
R597	Breast cancer (adjuvant) *	Multinational study			1	# 1 1	
EPOCH	Cancer chemotherapy associated anemia *	Japan	Commence of the Commence of th		Į.	1	
MRA	Multiple myeloma	France US	Account of the last of the las		 	+ 	
R340	Colorectal cancer, gastric cancer *	Japan	- Control of the cont		1	1	
R1415	Lung cancer	Japan	Commence and the latter to the commence of the latter than the		1	1	
CAL	Bone metastases  Hypercalcemia of malignancy	US Japan	Call Market Colon and Call Colon Col		: 	 	
AHM	Multiple myeloma	UK		T I	1	1	
CHC12103	Ovarian cancer  Non-small cell lung cancer	Japan	Continue de la Contin		1		
R435	Colorectal cancer	Japan		1	I I I	1	
R1273	Non-small cell lung cancer	Japan			!	1	
Bone and Joint	1		<del>1</del>		1	1	•
LY139481•HCI	Osteoporosis in postmenopausal women	Japan			The state of the state of	and the second	(Jan.04)
MRA	Rheumatoid arthritis	Japan EU		1			
ED-71	Osteoporosis	Japan	P-ID-M-ID-M			1	:
R484	Osteoporosis	Japan			 	 	
MRA	Juvenile idiopathic arthritis	Japan UK	Company of the control of the contro		: : ! :	! -!	
CHS13340	Osteoporosis	Japan	And the second s		1	1	:
Nephrology (Rena	al diseases)				·	<u> </u>	· · · · · · · · · · · · · · · · · · ·
PB-94	Hyperphosphatemia	Taiwan	Take Salar Inc.		T		⇒ (Jul.03)
EPOCH	Anemia in premature babies *	Japan	5			(Mar.02)	
R744	Renal anemia  Cancer chemotherapy associated anemia	Japan				 	
	vascular diseases						
SG-75	Acute heart failure *	Japan			1	(Jun.03)	:
AVS	Subarachnoidal hemorrhage	Japan			<u> </u>	(Apr.95)	
BO-653	Restenosis in post-PTCA  Coronary heart disease	Japan US		<u> </u>	: 	·	
Transplant, Immu	nology and Infectious diseases				·	· · · · · · · · · · · · · · · · · · ·	:
R442	Chronic hepatitis C	Japan		Launche	d Dec.03 ⊏		·
Ro64-0796	Prophylaxis of influenza in adults *	Japan				: == (Jun.03)	:
MRA	Castleman's disease (Orphan drug)	Japan US		<u> </u>	<u> </u>	(Apr.03)	
R964	Chronic hepatitis C	Japan	1 100 2 100 100 100 100 100 100 100 100	1	1	1	:
MRA	Crohn's disease	Japan	4 - 52 - 52 - 52 - 52 - 52 - 52 - 52 - 5	<del></del>	; ;	I	
MRA Other fields	Systemic lupus erythematodes (SLE)	US			1	I I	:
EPOCH	Predeposit of autologous blood transfusion *	Japan			1	(Mar.02)	:
FS-69	Enhancement of ultrasound images	Japan			Phas	e 2/3	
R212	Obesity	Japan			; ;	i i	
VAL	Post-hepatectomy/ Liver transplantation	Japan			: 	1	
GM-611	Decompensated cirrhosis  Gastroparesis (Diabetic / Idiopathic)	Japan Japan US			 	<u> </u> 	
	T. Company of the Com	. UO			I.	1	
R450	Stress urinary incontinence (SUI)	Japan			1	1	<del>-:</del>

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Injection   Roche / Genember   Anti-epidemal growth factor receptor (EGFR/-ER-1)   Injection   In-house   Humanized anti-PTHP monocoral antibody   Injection   In-house   Humanized anti-PTHP monocoral antibody   Injection   Cell Therapeutics   Poly-IL-glutamic acid-partitived conjugate   Pol	INN (Trade mark)	Dosage form	Origin (Collaborator)	Mechanism of Action
Injection Info.se Roche / Guerntech Humanzed anti-HERZ monoclosul anabody  Injection Info.se Rechel Humanzed anti-HERZ monoclosul anabody  Injection Info.se Rochel Humanzed anti-Human Lu5 receptor monoclorul anabody  Injection Info.se Rochel Humanzed anti-Human Lu5 receptor monoclorul anabody  Injection Info.se Humanzed anti-Human Lu5 receptor monoclorul anabody  Injection Info.se Humanzed anti-HTMP monoclorul antibody  Injection Info.se Humanzed anti-HTMP monoclorul antibody  Injection Info.se Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pady-Lubiusmo load-padiase conjugate  bevesaumab Injection Roche / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Generateth Humanzed anti-HTMP monoclorul antibody  Injection Info.se Pocno / Bective estogen receptor monoclorul antibody  Injection Info.se Pocno / Bective estogen receptor monoclorul antibody  Injection Info.se Pocno / Bective estogen receptor monoclorul antibody  Injection Info.se Pocno / Bective estogen receptor monoclorul antibody  Injection Info.se Pocno / Bective estogen receptor monoclorul antibody  Injection Info.se Pocno / Bective estogen receptor monoclorul antibody  Injection Info.se Pocno / Bective Estogen Poc				
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Injection   Roche / Genember   Anti-epidemal growth factor receptor (EGFR/-ER-1)   Injection   In-house   Humanized anti-PTHP monocoral antibody   Injection   In-house   Humanized anti-PTHP monocoral antibody   Injection   Cell Therapeutics   Poly-IL-glutamic acid-partitived conjugate   Pol		Injection	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody
Injection In-house Humanized anti-PTH/P monoclonal antibody Injection In-house Humanized anti-HM1,24 monoclonal antibody Injection Oell Therapeutos Poly-(L-glutamic acid-pacitaxet conjugate  bevacizumab Injection Roche / Genentech Humanized anti-VEGF (Vascular Endothelial Growth Fact monodonal antibody)  Injection Roche / Genentech Humanized anti-VEGF (Vascular Endothelial Growth Fact monodonal antibody)  Private Pt Italy Selective extragen receptor modulator  Injection In-house (Roche)  Injection In-house Pacisarium human enythropoletin  Injection In-house Pacisarium humani Li-6 receptor monoclona antibo Injection In-house Humanized anti-human III-6 receptor monoclona antibo Injection In-house Humanized anti-human III-6 receptor monoclonal antibo Injection In-house Humanized anti-human III-6 receptor monoclonal antibo Injection In-house Pacisarium enytherapeate Imaging  Injection In-house Pacisarium enytherapeate Imaging  Injection In-house Humanized anti-human III-6 receptor monoclonal antibo Injection In-house Humanized anti-human enythropoletin Injection In-house Injection In-h	capecitabine (Xeloda®)	Tablet	Roche	Antimetabolite, 5-FU derivative
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Injection   Roche / Generatech   Humanized anti-VEGF (Vascular Endothelial Growth Fact monocloral antibody)		Injection	In-house	Humanized anti-PTHrP monoclonal antibody
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ralaxifiene HCI (Evista***)  (Acternar**)  Injection  In-house  In-house  In-house  In-house In-house In-house In-house In-house In-house Injection In-house In-house In-house Injection In-house Injection In-house Injection Injection In-house Injection In-house Injection Inje	bevacizumab	Injection	Roche / Genentech	Humanized anti-VEGF (Vascular Endothelial Growth Factor) monoclonal antibody
Injection   In-house   Humanized anti-human IL-6 receptor monocional antibo injection   In-house   Activated Vitamin D derivative   Inhouse   Activated Vitamin D derivative   Inhouse   Inhouse   Activated Vitamin D derivative   Inhouse   Inhous	pertuzumab	Injection	Roche / Genentech	HER dimerization inhibitory humanized monoclonal antibod
Injection   In-house   Humanized anti-human IL-6 receptor monocional antibo   Injection   In-house   Roche   In-house   Activated Vitamin D derivative   Injection   Injecti	raloxifene HCI (Evista <sup>TM</sup> )	Tablet	Fii Lilly	Selective estrogen recentor modulator
Injection   In-house   Activated Vitamin D derivative			<u> </u>	
Oral   In-house   Activated Vitamin D derivative	, (66)		<u> </u>	Transmitted and transmitted of coopies monogenial and body
Injection   Cral   Injection   Cral   Injection   I		ļ <u>'</u>	<del> </del>	Activated Vitamin D derivative
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Injection In-house Hydroxyl radical scavenger  Capsule In-house Antioxidant  pegylated interferon alfa-2a (Pegasys®) Injection Roche Pegylated interferon alfa-2a (recombinant)  selfamilyir phosphate (Tamiflu®) Capsule Roche Influenza anti-viral agent  (Actemra™) Injection In-house (Roche)  ribavirin (Copegus™) Tablet Roche Anti-viral agent in combination with Pegasys® Injection In-house (Roche)  Tablet Roche Anti-viral agent in combination with Pegasys® Injection In-house Humanized anti-human IL-6 receptor monoclonal antibo Injection In-house (Roche) Humanized anti-human IL-6 receptor monoclonal antibo  Injection In-house (Roche) Humanized anti-human IL-6 receptor monoclonal antibo  epoetin beta (Epogin®) injection In-house Recombinant human erythropoietin Injection Alliance Ultrasound contrast agent for diagnostic imaging  orilistat (Xenical™) Capsule Roche Lipase inhibitor  valine Injection In-house Liver-regeneration promoting agent Recovery of liver function  mitemolinal fumarate Tablet In-house Motilin agonist Recovery of gastrointestinal motility  Oral Roche Alpha 14/1L adrenoceptor partial agonist		Injection	Roche	CERA (Continuous erythropoiesis receptor activator)
Injection In-house Hydroxyl radical scavenger  Capsule In-house Antioxidant  pegylated interferon alfa-2a (Pegasys®) Injection Roche Pegylated interferon alfa-2a (recombinant)  pegylated interferon alfa-2a (Pegasys®) Injection Roche Influenza anti-viral agent  (Actemra™) Injection In-house (Roche)  ribavirin (Copegus™) Tablet Roche Anti-viral agent in combination with Pegasys® Injection In-house (Roche)  Injection In-house (Roche) Humanized anti-human IL-6 receptor monoclonal antibo  Injection In-house (Roche) Humanized anti-human IL-6 receptor monoclonal antibo  Injection In-house (Roche) Humanized anti-human IL-6 receptor monoclonal antibo  Pepoetin beta (Epogin®) injection In-house Recombinant human erythropoietin  Injection Alliance Ultrasound contrast agent for diagnostic imaging  porlistat (Xenical™) Capsule Roche Lipase inhibitor  Valine Injection In-house Liver-regeneration promoting agent  Pecovery of liver function  Motilin agonist  Recovery of gastrointestinal motility  Oral Roche Alpha 14/1L adrenoceptor partial agonist	nicorandil (Sigmart®)	Injection	In-house	Potassium channel opener
Capsule   In-house   Antioxidant	· · · · · · · · · · · · · · · · · · ·			
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Injection   In-house   Humanized anti-human IL-6 receptor monoclonal antibo   Injection   In-house (Roche)   In-house (Roche)   In-house (Roche)   In-house   Anti-viral agent in combination with Pegasys®   Injection   In-house   Humanized anti-human IL-6 receptor monoclonal antibo   Injection   In-house (Roche)   Humanized anti-human IL-6 receptor monoclonal antibo   Injection   In-house (Roche)   Humanized anti-human IL-6 receptor monoclonal antibo   Injection   In-house   Recombinant human erythropoietin   Injection   In-house   Ultrasound contrast agent for diagnostic imaging   Injection   In-house   Lipase inhibitor   Injection   In-house   Liver-regeneration promoting agent   Recovery of liver function   In-house   In-house   Motilin agonist   Recovery of gastrointestinal motility   Oral   Roche   Alpha 1x/1L adrenoceptor partial agonist				
Injection   In-house (Roche)   Tablet   Roche   Anti-viral agent in combination with Pegasys®   Injection   In-house   Humanized anti-human IL-6 receptor monoclonal antibo   Injection   In-house (Roche)   Humanized anti-human IL-6 receptor monoclonal antibo   Humanized anti-human IL-6 receptor monoclonal antibo   Humanized anti-human IL-6 receptor monoclonal antibo   Humanized anti-human erythropoietin   Injection   In-house   Recombinant human erythropoietin   Injection   Alliance   Ultrasound contrast agent for diagnostic imaging   Profile to   Injection   In-house   Injection   In-house   Injection   In-house   Injection   Recovery of liver function   Recovery of liver function   In-house   Injection   In-house   Motillin agonist   Recovery of gastrointestinal motility   Oral   Roche   Alpha 14/1L adrenoceptor partial agonist				
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Injection   Alliance   Ultrasound contrast agent for diagnostic imaging		Injection	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody
Injection   Alliance   Ultrasound contrast agent for diagnostic imaging	epoetin beta (Epogin®)	injection	In-house	Recombinant human erythropoietin
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		Oral	Roche	
LUB FOUND   MOUNT CONTINUES		Oral	Roche	Insulin sensitizer

### **R&D: Strategy and System**

#### Reorganization of Research Laboratories

As a result of the reorganization of research laboratories that took place up until December 2003 — namely the closure of Takada Research Laboratories and the research division of CPUSA Chugai was able to integrate its research. functions to just four laboratories in Japan (Fuji-Gotemba, Kamakura, Tsukuba, and Ukima). Clinical development overseas will continue to take place at CPUSA and Chugai Pharma Europe Ltd. (CPE) in the U.K. In addition, the subsidiary Chugai Research Institute for Medical Science in Shizuoka Prefecture is responsible for certain areas of research. Chugai has about 850 staff within its domestic R&D functions as of the end of December 2003 (of these, about 280 are based in the Clinical Development Division) and boasts one of the leading R&D infrastructures in Japan.

#### O Four Domestic Research Sites and One Subsidiary

Research Laboratories	Main Research Activities				
Fuji-Gotemba Research Laboratories* (Shizuoka Pref.)	Drug discovery research, product research				
Kamakura Research Laboratories (Kanagawa Pref.)	Oncology-related drug discovery research, product research				
Tsukuba Research Laboratories* (lbaraki Pref.)	Antibody research				
Ukima Research Laboratories* (Tokyo)	Industrialization research, OTC research				
Chugai Research Institute for Medical Science (Shizuoka Pref.)	Transgenic research				

<sup>\*</sup>Biotechnology-related site.

### Establishment of a New Research & Development Group

With the organizational reforms carried out on October 1, 2003, Chugai set up a new Research & Development Group. This group consists of four departments within the strategy-related organization (Product Strategy Department, Development Planning Department, Development Information Department, and Intellectual Property Department), and two divisions related to the implementation (Research Division and Clinical Development Division). The Research & Development Group oversees all stages from research planning to clinical development and plays the role of improving efficiency, speed and success rates of projects.

At the same time, the two Clinical Development Divisions that were established after the merger

with Nippon Roche were integrated. The consolidation of the two former companies' standard operational procedures was also finalized and will be applied to drugs newly entering clinical trials, establishing a streamlined R&D system of Chugai.

#### Overseas Research Joint Ventures

In addition to its own laboratories, Chugai also has overseas joint ventures for its research activities; C&C Research Laboratories in Korea (synthetic chemistry research) and PharmaLogicals Research Pte., Ltd. in Singapore (genomic drug discovery research).

PharmaLogicals Research was established in May 2002 by three companies: Chugai (48%), Biostar Research Pte., Ltd. (48%) a subsidiary of Mitsui & Co., Ltd., and the Central Institute for Experimental Animals (4%). The aim of this laboratory is to explore new biopharmaceuticals by bringing together Chugai's drug discovery technology with human genome information and in-vivo experiments.

#### Strengthening the R&D Network

Roche places a significant importance on applying a "network" approach to research and development within its Group. This means that whilst maintaining independence of each company's own research and development activities, the members will collaborate in the form of joint projects, information and technology exchange when there are opportunities to improve overall efficiency.

As a member of the Roche Group, Chugai is actively looking for possibilities for collaboration within the group members. Already with Roche, it collaborates on small molecule discovery research, conducts joint development on the antibody drug MRA on a global basis, and exchanges information through the Joint Research Committee (twice annually) and the Joint Development Committee (three times annually).

Moreover, Chugai continues to strengthen its own R&D network through various collaborative activities and strategic partnerships by forming alliances with other companies, carrying out joint research with universities and research institutions, and participating in projects sponsored by the Japanese government.

#### **R&D Strategy**

Up to now, Chugai has strategically maintained its R&D expenditure at a high level. In the ninemonth period ended December 2003, R&D expenses were 43.5 billion yen, representing 18.7% of net sales. Chugai aims to keep its R&D expense ratio at an appropriate level through the synergistic effects of the alliance with Roche while, for the near term, maintaining expenses at 50 billion yen.

Chugai has set five strategic fields — oncology, renal diseases, bone and joint diseases, cardiovascular diseases, and transplant, immunology and infectious diseases — into which it is focusing its R&D expenditure. In these fields, the Company will accelerate its R&D in biopharmaceuticals centering on antibody drugs, while also continuing to make efforts in drug discovery through conventional synthetic chemistry.

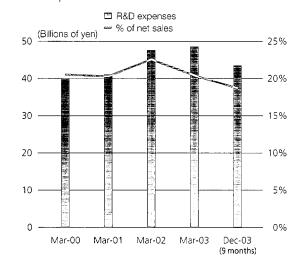
Chugai is now developing antibody drugs based on two types of technology: bio-production technology cultivated from experience with its two biopharmaceuticals Epogin® and Neutrogin®, and humanized antibody technology acquired from the Medical Research Council in the U.K. In order to improve efficiency in research, the Company has been conducting a unique research approach entitled "genomic antibody drug discovery" combining its antibody

and genomic drug discovery research that uses analyzed genetic information.

Currently, three antibody drugs — MRA, CAL and AHM (see p.15) — have entered clinical trials. The Company is also continuing its research into the discovery of novel target molecules, antibody drugs with new characteristics such as IgM and low molecular weight antibodies — areas where little development has been carried out in Japan.

Drug discovery technology by chemical synthesis is being markedly strengthened through the alliance with Roche. In addition to the benefits from the merger with Nippon Roche, Chugai has gained access to one of the world's largest synthetic compound libraries as a result of the collaborative agreement with Roche regarding small molecular synthetic drug research. The combined library, the prioritization of research themes and the promotion of technology exchanges with Roche are expected to dramatically increase efficiency in the selection of new pharmaceutical candidates from chemical compounds.

#### OR&D Expenses





Fuji-Gotemba Research Laboratories

### **Strategies to Develop Human Resources**

In October 2002, we introduced a new employee compensation system to commemorate the start of the new Chugai. Normally, in the case of a merger, company personnel systems are integrated one or two years after merging. However, in recognition of the globally intensifying competition within the pharmaceutical industry, we introduced a new system simultaneously with the integration in order for the early establishment of a competitive system and to maximize the synergistic effects resulting from the merger. More than one year has now passed since the integration of the two companies and, by unifying the standards for compensation systems, we believe that the integration of the two companies' differing corporate cultures has been greatly facilitated.

#### The New Employee Compensation System

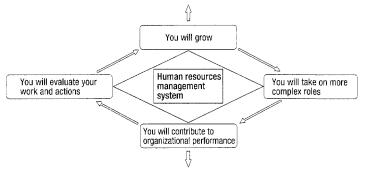
The new employee compensation system is performance-based, reflecting the fulfillment of individual roles. This system is designed not only to evaluate the short-term results but also to emphasize the medium- to long-term results of professional development that is considered particularly important for R&D-oriented pharmaceutical companies.

The basis of any compensation system should be the fair and reasonable evaluation of employees and their job performance. For this purpose, here at Chugai we created a system in which employees are able to thoroughly discuss their goals and achievements in quarterly-held interviews with their supervisors, with the results then assessed in performance evaluation meetings attended by all the assessors of related organizations.

Regarding compensation, we eliminated the seniority system and family allowance, and unified all base salaries into the current performance-based remuneration system. At the same time, we revised bonuses so that they are now allocated in accordance with company performance and adjusted the retirement benefits to reflect the performance of each employee. These retirement benefits are then determined in yearly performance evaluations.

#### Human Resources Management Cycle Based on Human Resources Development

Talented human resources who can function effectively worldwide



Creating a competitive company

#### Human Resource Development

Chugai places great emphasis on human resource development and the training of employees. To promote the development of professionals that are competitive on a global scale, we offer the following three training opportunities, and which are now showing most promising results: Management By Objectives (MBO, yearly basis); a Career Development Program (CDP, mid-to-long-term); as well as Off-The-Job training (OFF-JT, training outside the workplace) and self-development.

Although each employee is given the opportunity to develop their skills and capabilities through the challenging tasks in their daily work, supplementary training in the form of OFF-JT and support for self-development is also provided. To enhance the way these programs function as a system, we have established a new personnel training system consisting of 1) the Global Management Training Program, 2) the Corporate Program, 3) the Division Program and 4) the Self-Development Support Program.

We started the Global Management Training Program to discover and systematically train talented personnel at an early stage to create leaders able to promote innovative change. We also provide opportunities such as in-house training programs, collaborative exchanges with the Roche Group, and temporary transfers to affiliate companies overseas. Furthermore, we reinforced the Corporate Program, which is designed to promote the understanding of the Company goals, job development, and the enhancement of English skills. In addition to this, each division is developing its own unique training program to train sophisticated specialists.

With the CDP, not only do we encourage each employee to build a clear vision of their personal careers, we also conduct Career Interviews to which the top management, including the President, also attend in order that the Company can respond as effectively as possible to each employee's desire for self-actualization.

### **Promotion of Corporate Social Responsibility**

As a company that directly involved in human lives, Chugai has promoted activities that contribute to the environment and society and has also strengthened its compliance system. In fiscal year ended December 2003, we have further enhanced these activities by introducing the concept of Corporate Social Responsibility (CSR).

#### Basic Plan for Activities

Chugai's mission is to dedicate itself to adding exceptional value through the creation of innovative medical products and services for the benefit of the medical community and human health around the world. With this as our goal, we have made the dignity of human life our first priority and are pursuing corporate activities that are transparent, fair and highly ethical, as well as making important advances in the realm of science.

On October 1, 2002, we drew up a Mission Statement\* to accompany the start of the new Chugai, outlining the basic ideas behind our "Mission," "Core Values" and "Envisioned Future." Based on the core values, we redesigned the "Chugai Business Conduct Guidelines (Chugai BCG)"\* to create a specific guide for fulfilling our corporate responsibilities. Since then, our activities have been carried out based on both this Mission Statement and the Chugai BCG in order to fulfill our corporate social responsibility and become a company that answers the expectations of its stakeholders.

\* For more details regarding our Mission Statement and Chugai BCG, please see the following sites: http://www.chugai-pharm.co.jp /english/corporate for our Mission Statement and http://www.chugai-pharm.co.jp /english/corporate/bcg for Chugai BCG.

#### The System Supporting Our Activities

### 1. The Corporate Social Responsibility Committee

On October 1, 2003, we set up the Corporate Social Responsibility Committee, with the heads of the related administrative departments at Head Office forming the main body, and chaired by the Company's Deputy President. The committee meets twice annually, and as well as discussing ways to handle important issues relating to corporate social responsibility, it also is responsible for revising the activities scheduled for that fiscal year and decides the future activities and action plans for the next fiscal.

In addition, we have also established the Corporate Ethics Promotion Committee and Environmental Committee Secretariat through which we are able to inform and educate all of the Company's departments regarding key issues concerning our fiscal year plan and the promotion of social responsibility.

### 2. The Start of the Corporate Social Responsibility Promotion Department

On October 1, 2002, we set up a Corporate Ethics Department in order to establish and propagate throughout the Company an ethical awareness based on the aforementioned basic policy and behavior standards. Furthermore, we have been carrying out company-wide environmental activities with the Chugai Environmental Management System that is based on the Chugai Environmental Charter. (Previously, these activities were mainly carried out through the Environmental Affairs Section of the General Affairs Department.)

One year later, on October 1, 2003, we combined the Corporate Ethics Department and Environmental Affairs Section of the General Affairs Department to create the Corporate Social Responsibility Promotion Department. We made this move because corporate social responsibility is now positioned as one of the most important management issues worldwide.

Furthermore, with the International Organization for Standardization (ISO) having decided the international standards for corporate social responsibility for 2007 and with the Japanese government working to develop its own standards through the Ministry of Economy, Trade and Industry, we believe it is crucial that we deal with both environmental and social issues in a comprehensive way. By creating the Corporate Social Responsibility Promotion Department, we have now managed to establish a system that allows us to tackle from a wider perspective the various issues related to corporate social responsibility.

#### Specific Measures

#### 1. Corporate Ethics

(1) Study and Training in Corporate Ethics and Human Rights, and Educational Activities The BCG Study & Training Program began in the fiscal year ended March 2003 and is directed at all group employees. In its second year of running - fiscal year ended December 2003 - the program covered the basics of corporate social responsibility, legal issues (such as the Individual Information Protection Law and copyright problems), as well as problems concerning corporate ethics and human rights that employees may face within the workplace. Classes were held a total of 73 times with the aim of making participants aware of corporate social responsibility and of the importance of total compliance with the law. In addition to this, outside instructors offered 17 training sessions to line managers and senior line managers.

In the continuous effort to ensure all employees are both interested in and aware of these key topics, along with making educational posters and setting up an in-house website for employees, we also prepare and distribute Q&A booklets featuring common situations related to corporate ethics and human rights.

Moreover, for the past 10 years or so, we have been holding human rights' training sessions at each of our work sites in order to create a corporate climate that is respectful of this most important issue.

#### (2) BCG Hotline

To ensure all employees understand and respect the importance of social responsibility and compliance with the law, a BCG Hotline was set up in 2002, simultaneous with the introduction of the new system. Since it began operation we have received a variety of calls, testament to the success of the policies we have been implementing, such as the BCG Study and Training Program.

By working in coordination with the relevant divisions, our aim is to guarantee the prompt and effective response to each and every enquiry that is brought to our attention. In addition, a Sexual Harassment Hotline was also started, with callers able to contact the hotline from both inside and outside the Company. This hotline has been actively used as a means of protecting the mental health of employees as well as solving communication problems in the workplace. Those who handle the calls are trained to ensure that these matters are dealt with in both a sensitive and appropriate nature, with all emphasis on respecting the privacy of the caller.

#### 2. Measures to Promote Environmental Protection

(1) ISO 14001 Certification\* Acquisition In June 1998, Chugai's Fujieda Plant became the second facility within the Japanese pharmaceutical industry to acquire the ISO 14001 certification. Since then, five of our factories have now acquired this certification; however, as the one held by the Matsunaga Plant was returned in conjunction with its closure in December 2003, currently four are ISO 14001 certified.

\*ISO 14001, "certification" refers to the issuing of written assurance (the certificate) by an independent external body that has audited a company's management system and verified that it conforms to the requirements specified in the standard.

Source ISO Homepage: http://www.iso.ch/iso/en/iso9000-14000/ publicizing/publicizing\_6.html

(2) Reducing the Burden on the Environment
To reduce the burden on the environment,
Chugai is now working on ways to cut the
amount of generated industrial waste and promote
the efficient use of resources and energy at each
stage of production; from the research and

development of products to their manufacturing, sales and disposal.

We aim to reduce the volume of our carbon dioxide emissions at all of our sites by switching fuels, using more efficient boilers, and installing inverters in all our machinery and equipment.

In order to cut down on our generated waste volume, we began the recycling of waste aluminum hydroxide, which accounts for the majority of inorganic residue at our Fujieda Plant. As a result, we expect to be able to cut the final waste disposal volume at this plant by almost 55%. In appreciation of this measure, the Fujieda Plant was awarded the Reduce, Reuse & Recycle Promotion Council and Chairman's Prize. Moreover, at the time of the closure of our Matsunaga Plant, we promoted the reuse of appliances, furniture and fixtures that had been used at the plant by donating them to local governments and schools. This meant that fewer waste products were generated accompanying the closure of the plant.

As one of our policies to prevent air pollution, we have now stopped using all incinerators, with the one exception being the incinerator at the Chugai Research Institute for Médical Science, Inc. (see p.22). As usage of this incinerator cannot be avoided, we intend to promote energy and resource efficient countermeasures for pollution at this site.

In addition, in June 2003, we introduced 11 hybrid cars as vehicles to be used by our MRs. We plan to actively introduce more of these cars in the fiscal year ending December 2004.

High priority is now being placed on ways to reduce soil pollution. At the Kyushu Plant in Fukuoka Prefecture (operated by our wholly-owned subsidiary Eiko Kasei Co., Ltd. and closed in 1995), environmental tests revealed the presence of pollutants in the soil and underground water that exceeded the standard levels set by the Soil Pollution Countermeasures Law and the Residual Agricultural Chemicals Control Guidelines. Because this plant manufactured agricultural chemicals, the substances were discovered through a self-imposed investigation. Countermeasures to deal with this problem are scheduled to be drawn up in the near future after discussions with the prefectural and town governments.

We are also involved in a variety of other

activities to help alleviate the burden on the environment, such as cutting the amount of harmful chemical substances we use — namely pyridine, toluene and formaldehyde — controlling the quality of our drainage water, promoting the purchase of green products, and developing products that take environmental protection issues into account.

(3) Disclosure of Environmental Information Since June 2001, we have been publishing an annual Environmental Report. This report can be found on our website at http://www.chugai-pharm.co.jp/ english/corporate/environmental

#### 3. Contribution to Society

Up to now, Chugai has supported several activities in its aim to better contribute to society. One of these that we have been carrying out for some time is the provision of monetary assistance for pharmaceutical research, research grants, and scholarships as well as assistance to international joint research through the Tokyo Biochemical Research Foundation\*. Another is the donation of specially equipped para-transit vehicles to welfare services. Over the past 20 years, we have donated more than 100 such vehicles to welfare services throughout Japan.

\* The Tokyo Biochemical Research Foundation was established in 1960 with the purpose of conducting basic research related to medical treatment and new pharmaceuticals, assisting such research, supporting the fostering of promising researchers, and contributing to creative research on the pharmaceuticals that are most needed in Japan.

Furthermore, since the establishment of the Japan Marrow Donor Program, we have been providing assistance to several activities aimed at educating people about marrow transplants and registering donors. In 2003, we supported for the third time the José Carreras Tenor Recital "Volunteer for Life."

Moreover, in Japan we have been conducting our own regional clean-up activities at all our sites. Overseas, we have also been supporting fund-raising activities and cancer societies.

### **Corporate Governance**

Chugai pursues corporate governance that is consistent with global standards as an autonomous, listed company, promoting its business independently in Japan and overseas as well as as a member of the Roche Group.

### Chugai's Corporate Governance Policy and Practices

To strengthen the function of the Board of Directors and accelerate the decision-making system, Chugai has adjusted the Board's size and has appointed outside directors to enhance management transparency. As of October 2002, Chugai's Board of Directors consists of 11 members, including five outside directors (as of March, 2004). Furthermore, the Company has also adopted an executive officer system to identify the responsibilities of each business operation.

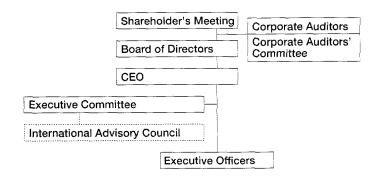
The Executive Committee is comprised of primary executive officers and is responsible for making critical decisions in conducting business operations entrusted by the Board. The Executive Committee then notifies the Board of all the important decisions it makes. Moreover, to boost morale and retain exceptional talent, we instituted the stock option system in 2003, and in August

2003 distributed stock options to internal directors and key employees for the first time.

Chugai's auditing system currently involves four corporate auditors (two of whom are outside auditors). In October 2003, a new auditing team consisting of two members was established to further strengthen the corporate auditing function. In addition, the Audit Department operates to internally monitor business operations.

In addition to the above, we run an International Advisory Council (IAC) whose members are specialists in various fields from Japan, Europe and the U.S. in order to seek a broad range of opinions from diverse perspectives. The IAC meets twice a year with additional meetings and individual meetings scheduled where necessary. At these meetings, IAC members provide Chugai's senior management with useful advice on corporate governance, company management, business conduct and other issues.

#### Corporate Governance System



#### Members of the International Advisory Council

#### Prof. Victor Halberstadt

Professor of Economics, Leiden University

#### Dr. Keith Jones

Non-executive Chairman of the European Medicines Evaluation Agency (EMEA),

#### Dr. Gerald D. Laubach

Retired President & COO, Pfizer Inc.

#### Dr. Andres Leuenberger

Vice Chairman, Roche Holding Ltd.

#### Judge Abraham D. Sofaer

George P. Shultz Distinguished Scholar and Senior Fellow, Hoover Institution, Stanford University Prof. Dr.

#### Prof. Dr. Dieter E.H. Spethmann

Retired Chairman and CEO, Thyseen Stee

#### Mr. Goro Watanabe

Retired Chairman, Mitsui Chemicals, Inc.

(As of March 25, 2004)



Standing from left:

Motoo Ueno

Executive Vice President

Executive Vice President

Executive Vice President

Seated from left:

Deputy President

Osamu Nagayama President, CEO

Ryuzo Kodama Executive Vice President, CFO

**Board Members** 

Osamu Nagayama

Chairman of the Board, President, CEO

Motoo Ueno

Deputy President

Ryuzo Kodama

Executive Vice President, CFO

Akira Okazaki

Executive Vice President Managing Director of Technology & Production Group

Yasuo Maeno

Executive Vice President, Managing Director of Sales & Marketing Group

Dr. Tatsumi Yamazaki

Executive Vice President, Managing Director of Research & Development Group

Dr. Etsuro Ogata

Director Emeritus of Cancer Institute Hospital

Abraham E. Cohen

Chairman, Chugai Pharma USA

Dr. Franz B. Humer

Chairman and Chief Executive Officer, F. Hoffmann-La Roche Ltd.

William M. Burns

Head of Pharmaceuticals Division, F. Hoffmann-La Roche Ltd.

Prof. Dr. Jonathan K.C. Knowles

President of Global Research, F. Hoffmann-La Roche Ltd.

Corporate Auditors

Tsuguo Ogasawara

Takao Honma

Yasunori Fujii

Toshio Kobayashi

**Executive Officers** 

Osamu Nagayama Chairman of the Board, President, CEO

Motoo Ueno

Deputy President

Ryuzo Kodama Executive Vice President, CFO

Akira Okazaki

Executive Vice President, Managing Director of Technology & Production Group

Yasuo Maeno

Executive Vice President, Managing Director of Sales & Marketing Group

Dr. Tatsumi Yamazaki

Executive Vice President, Managing Director of Research & Development Group

Hironobu Komiya

Senior Vice President, Regulatory Affairs, Drug Safety, Quality Assurance

Harutaka Fujita

Senior Vice President, Corporate Social Responsibility, Human Capital & Personnel, General Manager of General Affairs Dept

Tatsuro Kosaka

Vice President, General Manager of Corporate Planning Dept.

Dr. Hiroyuki Ohta

Vice President, Development in Europe & U.S.A.

Fumihiko Kamoshida

Vice President, General Manager of Legal Affairs Dept.

Yuichiro Onitsuka

Vice President, General Manager of External Affairs Dept.

Vice President, Department Manager of Development Planning Dept.

Dr. Mikio Arisawa

Vice President General Manager of Research Div.

Koichi Shoji

Vice President

General Manager of Clinical Development Div.

Dr. Eigoro Murayama

Vice President, General Manager of Pharmaceutical Technology Div.

Tomoyuki Nakayama

Vice President.

Regulatory Affairs Audit,

General Manager of Pharmaceutical Production Div.

Masaharu Unno

Vice President.

Wholesaler Business Planning, Sales & Marketing Education & Training

Motoo Saito

Vice President,

General Manager of Product Lifecycle & Medical Information Div.

Naotaka Nakamura

Vice President,

General Manager of Medical Business & Science Div

Yoichi Yamanaka

General Manager of Sales Coordination Div.

Kazunori Komiyama

Vice President,

Branch Manager of Tokyo Branch 1

Akira Suzuki

Branch Manager of Osaka Branch

Yoshinori Hibino

Vice President,

General Manager of International Business Div.

Toshiki Yagi

Vice President,

President of Healthcare Company

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West Japan Sales Dept

30

	Millions o	Millions of yen except per share amount and other statistics				Thousands of U.S. dollars	
	Nine months ended					Nine months ended	
	December 31,				d March 31	December 31,	
	2003	2003	2002	2001	2000	2003	
Results for the year:							
Net sales	¥232,748	¥237,391	¥211,705	¥203,005	¥195,506	\$2,175,215	
Gross profit	149,207	158,006	146,743	140,959	136,511	1,394,458	
Selling, general and administrative expenses	62,963	79,178	72,189	69,527	66,540	588,439	
Research and development expenses	43,525	48,511	47,845	41,189	39,993	406,776	
Operating income	42,719	30,317	26,709	30,243	29,978	399,243	
Net income (loss)	28,446	(20,135)	14,598	15,500	8,761	265,850	
Capital investments	11,819	17,815	14,292	9,689	13,321	110,458	
Depreciation and amortization	10,514	14,905	12,939	14,408	14,462	98,262	
Amounts per share (Yen and U.S. dollars):							
Net income (loss) -basic	¥ 51.73	¥ (51.75)	¥ 57.93	¥ 61.70	¥ 35.53	\$ 0.48	
Cash dividends	13.00	16.00	16.00	16.00	13.00	0.12	
Financial position at year-end:						٠	
Total assets	¥405,197	¥425,301	¥349,226	¥340,174	¥321,087	\$3,786,888	
Property, plant and equipment, net	91,970	93,969	81,445	77,798	80,225	859,533	
Long-term debt	10,750	11,968	26,269	66,279	66,512	100,467	
Total shareholders' equity	296,717	277,254	200,779	190,257	170,972	2,773,056	
Other statistics:							
Number of employees	5,680	5,774	4,964	4,931	4,877		

Note: The accompanying notes to the consolidated financial statements are an integral part of this summary.

Due to the change in financial year-end from March 31 to December 31, the accounting period for the fiscal year ended December 2003 was for the nine months from April 1, 2003 to December 31, 2003. Therefore, a comparison of performance figures with those from the previous fiscal year is not provided.

#### Operating Environment and Chugai's Strategy

Over 90% of Chugai's sales are from prescription pharmaceuticals mainly in the Japanese market. The prescription pharmaceutical industry has been operating in an extremely harsh environment in recent years due to measures taken by governments in developed countries, including Japan, to curtail medical expenses, the expansion of global competition and rising R&D costs. As a result, companies in the industry are now pursuing a variety of strategies to maintain their competitive advantages. Chugai's took the form of the strategic alliance with F. Hoffmann-La Roche Ltd., one of the top pharmaceutical companies in Europe, located in Basel, Switzerland. (Since October 1, 2002, Roche has obtained 50.1% of Chugai's shares through its wholly owned subsidiary, Roche Pharmholding B.V.) As part of the alliance, Chugai merged with Nippon Roche on October 1, 2002, thereby strengthening its drug development and marketing platforms and increasing its competitive edge. In the Japanese prescription pharmaceutical market, Chugai ranked fourth in terms of net sales in 2003, with a 4.1% market share.

### Business Results in Fiscal Year Ended December 2003 Net sales

Net sales in the fiscal year under review totaled 232.7 billion yen (3.4% higher than the initial forecast). By business segment, in prescription pharmaceuticals we

posted sales of 218.2 billion yen, despite the harsh business environment. There was a decline in sales of some products such as Alfarol®, an agent for osteoporosis; however, business was steady for Epogin®, an agent for anemia associated with end-stage renal disease, as well as Rituxan® and Herceptin®, both anti-tumor agents, and the anti-influenza agent Tamiflu®. An injectable, bag form of Rocephin®, which is a cephem-type antibiotic ceftreaxone sodium, the anti-tumor agent Xeloda®, and the hyperphosphatemia treatment Renagel® were all launched in June 2003 and notably contributed to the overall sales.

Sales of nonprescription products (over-the-counter pharmaceuticals) came to 14.6 billion yen. While sales of nutritional supplement drinks greatly benefited from the redesigned packages of Guronsan® and the more reasonable pricing of New Guromont®, there was a large drop in sales of Varsan® (insecticide products for household use) due to the cool summer.

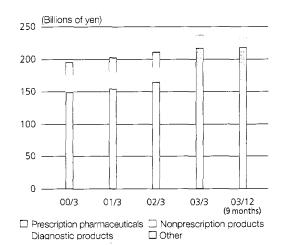
Overseas sales amounted to 16.8 billion yen, and the ratio of overseas sales to net sales was 7.2%.

\*The major products that make up overseas sales are the neutropenia agent lenograstim (Neutrogin® in the Japanese market) and the antianginal agent nicorandil (Sigmart®).

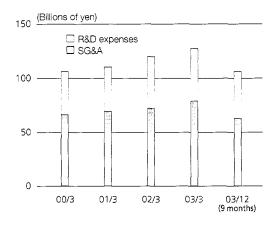
#### © Costs and expenses

Cost of sales amounted to 83.5 billion yen. Since a greater percentage of Roche products were included in our sales, the ratio of cost of sales to net sales rose by 2.5 percentage points to 35.9%. Excluding research and development expenses, the selling, general and administrative expenses amounted to 63.0 billion yen. Research and development expenses totaled 43.5 billion yen, with a ratio to net sales of 18.7% (20.4% in the previous fiscal year.)

#### **Net Sales**



#### SG&A and R&D Expenses



#### © Earnings

Operating income in the fiscal year under review totaled 42.7 billion yen, with the higher sales of prescription pharmaceuticals and the overall, more efficient rate of expenditure. The ratio of operating income to net sales increased by 5.6 percentage points to 18.4%.

Other incomes include 3.5 billion yen from the gain on the disposition of the fixed assets of former Takada Research Laboratories, 3.3 billion yen as milestone payments based on the license agreement with Roche for the co-development and co-promotion of the antibody drug MRA, and a 1.3 billion yen gain on sales of investment securities. In total, after taking into account the other incurred expenses of 2.8 billion yen resulting from loss on disposition of equipment and environmental recovery cost under termination activities, we posted a net income of 28.4 billion yen (29.3% higher than the initial forecast).

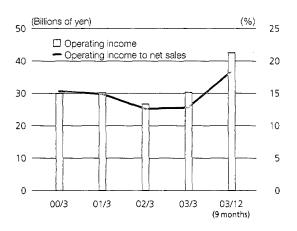
#### Financial Position and Liquidity

#### © Financial position

After the payment of income taxes of 31.4 billion yen related to the spin-off of Gen-Probe Incorporated, our total assets as of December 31, 2002 were 405.2 billion yen, down 20.1 billion yen from the previous fiscal year-end. Total liabilities were 107.6 billion yen, 38.8 billion yen lower than the previous fiscal year-end following debt repayments. With a net working capital (defined as current assets minus current liabilities) recording at 199.2 billion yen, and a current ratio of 453.8%, Chugai is in a sound financial position.

Shareholders' equity totaled 296.7 billion yen, a 19.5 billion yen increase from the previous fiscal year-end. The ratio of shareholders' equity rose from 65.2% in the previous fiscal year to 73.2% in the fiscal year under review.

#### Operating Income and Ratio



#### © Cash flows

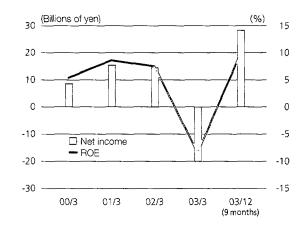
Net cash used in operating activities amounted to 36.8 billion yen, partly resulting from the payment of 53.6 billion yen for income taxes.

Net cash provided by investing activities amounted to 14.4 billion yen, partly due to proceeds from the sale of marketable securities that generated 62.4 billion yen.

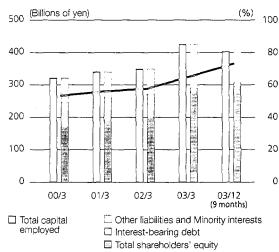
Net cash used in financing activities totaled 11.6 billion yen, due to a net increase in treasury stock of 5.9 billion yen, and 4.4 billion yen for payments of cash dividends.

As a result, cash and cash equivalents at the end of the fiscal year under review were 36.2 billion yen, 34.4 billion yen lower than the outstanding balance at the beginning of the fiscal year.

#### Net Income and ROE



#### Composition of Total Capital Employed



- Ratio of total shareholders' equity to total capital employed

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## Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries December 31, 2003 and March 31, 2003

		·11: C	Thousands of U.S. dollars
-		illions of yen	(Note 3)
A	December 31,	March 31,	December 31,
Assets	2003	2003	2003
Current assets:			
Cash and cash equivalents	¥ 36,226	¥ 70,593	\$ 338,561
Marketable securities including short-term investments (Note 12)	30,695	47,284	286,869
Receivables:			
Trade notes	12,488	12,588	116,710
Trade accounts	101,373	85,141	947,411
Other	10,501	3,369	98,140
Reserve for doubtful accounts	(649)	(470)	(6,065)
Inventories (Note 4)	53,157	40,817	496,794
Deferred tax assets (Note 9)	9,502	14,301	88,804
Other	2,211	2,914	20,664
Total current assets	255,504	276,537	2,387,888
Land Buildings and structures Machinery and equipment Construction in progress	10,939 102,309 98,489 6,669	103,491 97,418 8,807	956,159 920,458 62,327
	218,406	222,332	2,041,178
Accumulated depreciation (Note 5)	(126,436)	(128,363)	(1,181,645)
Property, plant and equipment, net	91,970	93,969	859,533
Investments and other assets: Investment securities (Note 12) Unconsolidated subsidiaries and affiliates	17,042 60	20,585	159,271 561
Long-term loans	163	184	1,523
Lease deposits	3,720	3,827	34,766
Deferred tax assets (Note 9)	20,809	20,128	194,477
Other	15,929	10,011	148,869
Total investments and other assets	57,723	54,795	539,467
Total assets	¥ 405,197	¥ 425,301	\$3,786,888



2	c

•	N	Tillions of yen	Thousands of U.S. dollars (Note 3)
	December 31,	March 31,	December 31,
Liabilities and shareholders' equity	2003	2003	2003
Current liabilities:			
Long-term debt due within one year (Note 6)	¥ 11	¥ 140	\$ 103
Payables (Note 17):			
Trade notes	133	844	1,243
Trade accounts	20,472	16,131	191,328
Construction	4,718	8,369	44,093
Other	5,883	9,293	54,981
Income taxes payable (Note 9)	242	31,670	2,262
Deferred tax liabilities (Note 9)	4	8	37
Accrued liabilities	20,782	21,385	194,224
Other	4,059	3,733	37,935
Total current liabilities		91,573	526,206
Long-term liabilities:			
Long-term debt (Notes 6 and 17)	10,750	11,968	100,467
Deferred tax liabilities (Note 9)		16	168
Reserve for employees' retirement benefits (Note 10)	39,558	42,309	369,701
Reserve for officers' retirement benefits	511	460	4,776
Other	435	32	4,066
Total long-term liabilities		54,785	479,178
Minority interests in consolidated subsidiaries	904	1,689	8,448
Contingent liabilities (Note 15)			
Shareholders' equity (Notes 7 and 19):			
Common stock, without par value:			,
Authorized: 799,805,050 shares			
Issued:			
December 31, 2003 – 550,691,219 shares	68,237		637,729
March 31, 2003 – 550,633,518 shares		68,215	057,727
Additional paid-in capital		88,078	823,355
Retained earnings	•	120,114	1,346,374
Net unrealized holding gain on securities		1,025	21,879
Translation adjustments		(109)	(804)
Treasury stock, at cost		(69)	(55,477)
Total shareholders' equity		277,254	2,773,056
	¥ 405,197	¥ 425,301	\$3,786,888
Total liabilities and shareholders' equity	± 4UJ,17/	± <del>1</del> 423,301	\$J,/\$U,088

Note: The accompanying notes are an integral part of these consolidated statements.

Consolidated Statements of Operations Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries Nine months ended December 31, 2003, Years ended March 31, 2003 and 2002

		М	illions of yen	Thousands of U.S. dollars (Note 3)
	Nine months ended	Years ended March 31 2003 2002		Nine months ended
1	December 31,			December 31,
	2003			2003
Net sales	¥ 232,748	¥ 237,391	¥ 211,705	\$2,175,215
Cost of sales (Note 17)	83,541	79,385	64,962	780,757
Gross profit		158,006	146,743	1,394,458
Selling, general and administrative expenses	62,963	79,178	72,189	588,439
Research and development expenses	43,525	48,511	47,845	406,776
Operating income	42,719	30,317	26,709	399,243
Other income (expenses):				
Interest and dividend income	423	503	679	3,953
Interest expense (Note 17)	(210)	(277)	(959)	(1,962)
Equity in earnings of affiliated companies			957	_
Other (Note 8)	6,312	(23,683)	(1,093)	58,990
	6,525	(23,457)	(416)	60,981
Income before income taxes and minority interests	49,244	6,860	26,293	460,224
Income taxes (Note 9)	19,797	26,479	11,673	185,019
Minority interests	(1,001)	(516)	(22)	(9,355)
Net income (loss) (Note 18)	¥ 28,446	¥ (20,135)	¥ 14,598	\$ 265,850

Note: The accompanying notes are an integral part of these consolidated statements.

# Consolidated Statements of Shareholders' Equity

Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries Nine months ended December 31, 2003, Years ended March 31, 2003 and 2002

		М	illions of yen	Thousands of U.S. dollars (Note 3)
	Nine months	141	inions of yen	Nine months
	ended			ended
	December 31,		ed March 31	December 31,
	2003	2003	2002	2003
Common stock (Note 7):				
Balance at beginning of year	¥ 68,215	¥ 24,035	¥ 23,994	\$ 637,523
Add:				
Issuance of capital stock in accordance with merger agreement (Note 7)	_	18,782	_	_
Conversion of convertible bonds	22	25,651	41	206
Exercise of warrants (Note 7)		18,807		_
Deduct:				
Capital reduction due to spin-off of Gen-Probe Incorporated (Note 7)	_	(19,060)		-
Balance at end of year	68,237	68,215	24,035	637,729
Additional paid-in capital (Note 7):				
Balance at beginning of year	88,078	35,181	35,140	823,159
Add:				
Issuance of capital stock allocated to				
Roche Pharmholding B. V. upon merger (Note 7)	_	8,800	_	
Issuance of capital stock in accordance with merger agreement (Note 7)		18,782	<del>-</del>	_
Conversion of convertible bonds	21	25,610	41	196
Exercise of warrants (Note 7)		18,765	_	_
Gain on disposal of treasury stock	0	_	_	0
Deduct:				
Capital reduction due to spin-off of Gen-Probe Incorporated (Note 7)		(19,060)	25.50	
Balance at end of year	88,099	88,078	35,181	823,355
Retained earnings (Note 7):	120.11/	127 100	105.105	
Balance at beginning of year	120,114	137,189	127,135	1,122,561
Net income (loss)	28,446	(20,135)	14,598	265,850
Cash dividends	(4,405)	(4,457)	(4,410)	(41,168)
Increase in retained earnings resulting from merger		11,450	_	_
Decrease in retained earnings due to decrease in		(2.500)	(71)	
shareholding in a consolidated subsidiary	_	(3,590)	(71)	_
	(93)	(280) (63)	(63)	(869)
Other Balance at end of year		120,114	137,189	1,346,374
Net unrealized holding gain on securities:	144,002	120,114	137,109	1,340,3/4
Balance at beginning of year	1,025	2,528	5,211	9,580
Net change during year		(1,503)	(2,683)	12,299
Balance at end of year	2,341	1,025	2,528	21,879
Translation adjustments:	2,541	1,027	2,720	21,0/
Balance at beginning of year	(109)	1,915	(1,219)	(1,019)
Net change during year	23	(2,024)	3,134	215
Balance at end of year		(109)	1,915	(804)
Treasury stock, at cost:	(00)	(20)	-,,-,	(001)
Balance at beginning of year	(69)	(69)	(4)	(645)
Net change during year	, ,	(0)	(65)	(54,832)
Balance at end of year		(69)	(69)	(55,477)
Total shareholders' equity		¥ 277,254	¥ 200,779	\$2,773,056
	- 11		,, , , , , , , , , , , , , , , , , , ,	

	Nine months ended December 31,	Years end	ded March 31
	2003	2003 -	2002
Number of shares of common stock:			
Balance at beginning of year	550,633,518	252,068,564	252,000,233
Add:			
Issuance of capital stock allocated to			
Roche Pharmholding B. V. upon merger (Note 7)		196,628,960	_
Issuance of capital stock in accordance with merger agreement (Note 7)	,	21,103,544	
Conversion of convertible bonds	57,701	52,957,790	68,331
Exercise of warrants (Note 7)	_	28,069,610	_
Deduct:			
Retirement of treasury stock	_	(194,950)	_
Balance at end of year	550,691,219	550,633,518	252,068,564

Note: The accompanying notes are an integral part of these consolidated statements.

Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries Nine months ended December 31, 2003, Years ended March 31, 2003, 2002

		N.	fillions of yen	Thousands of U.S. dollars (Note 3)
	Nine months ended			Nine months ended December 31,
	2003	2003	2002	2003
C.1 fl. fr.		2003	2002	
Cash flows from operating activities	v 40.244	¥ 6,860	V 26 202	\$ 460.224
Income before income taxes and minority interests		,	¥ 26,293	\$ 460,224
Depreciation and amortization		14,905	12,939	98,262
Interest and dividend income		8,237	3,883	(25,692)
		(503)	(679)	(3,953)
Interest expense		277	959	1,962
Equity in earnings of affiliated companies		272	(957)	2.710
Loss on disposal of fixed assets		372	880	3,710
Gain on sales of fixed assets			- 2 271	(32,402)
(Gain) loss on sales and revaluation of investment securities		(67)	3,271	(11,925)
(Increase) decrease in notes and accounts receivable		(9,966)	2,783	(151,168)
Increase in inventories		(1,561)	(102)	(115,551)
Increase (decrease) in notes and accounts payable		5,756	(642)	34,150
(Decrease) increase in accrued consumption tax		986	(867)	(13,365)
Other	(9,491)	7,659	2,361	(88,701)
Subtotal	16,644	32,955	50,122	155,551
Interest and dividends received	_	594	717	3,953
Interest paid	. ,	(426)	(959)	(2,009)
Income taxes paid		(10,567)	(20,205)	(501,374)
Net cash (used in) provided by operating activities	(36,795)	22,556	29,675	(343,879)
Cash flows from investing activities	((0.006)	(5(005)	(2 ( == 1)	(202.206)
Purchases of marketable securities		(76,027)	(34,771)	(382,206)
Proceeds from sales of marketable securities		73,970	15,095	583,150
Purchases of investment securities		(9,094)	(9,432)	(16,841)
Proceeds from sales of investment securities	3,893	5,365	13,730	36,383
Purchases of fixed assets	(15,973)	(14,366)	(14,528)	(149,280)
Proceeds from sales of fixed assets		1,522	209	67,682
Net (increase) decrease in short-term loans		50	75	(47)
Net decrease in long-term loans	6	1,608	332	56
Additional acquisition of shares of consolidated subsidiaries		(140)	(1)	(4,187)
Proceeds from sales of investments in subsidiaries		1,087	(20, 201)	
Net cash provided by (used in) investing activities	14,414	(16,025)	(29,291)	134,710
Cash flows from financing activities  Net decrease in short-term bank loans		(2 (00)	(120)	
	(1.302)	(3,690)	(120)	(12.169)
Net decrease in long-term debt		(95)	(348)	(12,168)
Redemption of bonds		(9,982)	_	(0)
Proceeds from issuance of common stock (Note 7)		37,564		_
Decrease resulting from reduction in capital	(5.967)	(12,494)	_	(54,832)
Net increase in treasury stock	(5,867)	(280)	(4 410)	,
Cash dividends paid	(4,405)	(4,457)	(4,410)	(41,168)
Cash dividends paid to minority shareholders	(8)	(17)	(7.6)	(75)
Other  Net cash (used in) provided by financing activities	(11 592)	6 5 4 0	(74)	(109.242)
	(11,582)	6,549	(4,952)	(108,243)
Effect of exchange rate changes on cash and cash equivalents	(333)	12 806	(3,628)	(3,111)
Cash and cash equivalents at beginning of year		12,806 53,426		(320,523)
Cash increase upon merger	70,593	53,426 16,421	57,161	659,748
Cash decrease resulting from exclusion of subsidiaries from consolidation	(71)	(12,060)	(107)	(664)
Cash and cash equivalents at end of year	¥ 36,226	¥ 70,593	¥ 53,426	
Note: The accompanying notes are an integral part of these consolidated statements	т Э0,440	т / U, J У Э	± 33,420	\$ 338,561

Note: The accompanying notes are an integral part of these consolidated statements.

# 1. Basis of financial statements

Chugai Pharmaceutical Co., Ltd. (the "Company") and its domestic consolidated subsidiaries maintain their books of account in accordance with accounting principles and practices generally accepted and applied in Japan, and its overseas subsidiaries maintain their books of account in conformity with those of their countries of domicile.

The accompanying consolidated financial statements have been compiled from the consolidated financial statements prepared by the Company as required by the Securities and Exchange Law of Japan and have been prepared in accordance with accounting principles and practices generally accepted in Japan, which may differ in certain respects from accounting principles and practices generally accepted in countries and jurisdictions other than Japan. Certain modifications of, and reclassifications in, the presentation of the accompanying financial statements, including the presentation of statements of shareholders' equity, have been made to facilitate understanding by readers outside Japan.

The Company changed its financial year end from March 31 to December 31 in order to adopt the F. Hoffmann-La Roche Ltd. ("Roche") calendar-based fiscal year as a member of the Roche Group. This change was approved by the shareholders of the Company at its annual general meeting held on June 25, 2003.

# 2. Significant accounting policies

# (a) Basis of consolidation and accounting for investments in unconsolidated subsidiaries and affiliates

The consolidated financial statements include the accounts of the Company and significant companies which it controls directly or indirectly. All significant intercompany accounts and transactions have been eliminated in consolidation.

The excess of cost over net assets acquired with respect to the consolidated subsidiaries is amortized on a straight-line basis over a period of twenty years or amortized fully when acquired if the amount is immaterial.

Investments in companies which are not consolidated or accounted for by the equity method are carried at cost or less. Where there has been a permanent decline in the value of such investments, the Company has written them down.

#### (b) Foreign currency translation

The revenue and expense accounts of the overseas consolidated subsidiaries and their balance sheet accounts, except for the components of shareholders' equity, are translated into yen at the rates of exchange in effect at the balance sheet date. The components of shareholders' equity are translated at their historical rates. Translation differences are presented as translation adjustments in shareholders' equity.

#### (c) Cash equivalents

Cash equivalents consist principally of cash in banks, money market funds and highly liquid investments with maturities of three months or less when purchased.

#### (d) Inventories

Inventories other than work in process are stated at cost determined principally by the average cost method. Work in process is stated at cost determined principally by the first-in, first-out method.

#### (e) Depreciation

Depreciation of property, plant and equipment is calculated primarily by the declining-balance method at rates based on the estimated useful lives of the respective assets.

# (f) Leases

Non-cancelable leases are primarily accounted for as operating leases (whether such leases are classified as operating or finance leases) except that leases which stipulate the transfer of ownership of the leased assets to the lessee are accounted for as finance leases.

# (g) Securities

Securities other than those issued by subsidiaries and affiliates are classified into three categories; trading, held-to-maturity or other securities. Trading securities are carried at fair value and held-to-maturity securities are carried at amortized cost. Marketable securities classified as other securities are carried at fair value with any changes in unrealized holding gain or loss, net of the applicable income taxes, included directly in share-holders' equity. Non-marketable securities classified as other securities are carried at cost. If the value of the marketable securities classified as other securities has declined significantly, such securities are written down to fair value thus establishing a new cost basis, and the amount of each write-down is charged to income as an impairment loss unless the fair value is deemed to be recoverable.

#### (h) Retirement benefits

The reserve for employees' retirement benefits is stated at the amount required to cover the liability as of the balance sheet date and is based on the Company's estimate of its liability for retirement benefits and its pension fund assets as of the balance sheet date.

The retirement benefit obligation is attributed to each period by the straight-line method over the estimated years of service of the employees.

Prior service cost is being amortized as incurred by the declining-balance method over a period (10 years) which is shorter than the average remaining years of service of the participants in the plans.

Actuarial gain and loss are amortized in the year following the year in which the gain or loss is recognized by the declining-balance method over a period (10 years) which is shorter than the average remaining years of service of the participants in the plans.

Directors and corporate auditors are not covered by the retirement benefit plans referred to above. However, the liability for their retirement benefits are calculated based on management's estimate of the amounts which would be payable if these corporate officers resigned their offices as of the balance sheet date. Amounts payable to directors and corporate auditors upon retirement are subject to the approval of the shareholders.

# Notes to Consolidated Financial Statements

# (i) Research and development expenses

Research and development expenses are charged to income when incurred.

# (i) Income taxes

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the assets and liabilities and are measured using the statutory tax rates which will be in effect when the differences are expected to be realized.

# (k) Derivative financial instruments

The Company has entered into various derivative transactions in order to manage certain risks arising from adverse fluctuations in foreign currency exchange rates and interest rates. Derivatives are carried at fair value with any changes in unrealized gain or loss charged or credited to operations.

# (l) Accounting standard for treasury stock and reduction of legal reserve

Effective the year ended March 31, 2003, the Company and its domestic consolidated subsidiaries adopted a new accounting standard for treasury stock and reduction of legal reserves. The adoption of this new accounting standard had no impact on the operating results for the year ended March 31, 2003.

# (m) Appropriation of retained earnings

Under the Commercial Code of Japan (the "Code"), the appropriation of retained earnings with respect to a given financial period is made by resolution of the shareholders at a general meeting held subsequent to the close of such financial period. The accounts for that period do not, therefore, reflect such appropriations. Refer to Note 19.

# (n) Reclassifications

Certain amounts in the prior year's financial statements have been reclassified to conform to the presentation for the nine months ended December 31, 2003. These changes had no impact on the previously reported results of operations or on shareholders' equity.

# 3. U.S. dollar amounts

The U.S. dollar amounts in the consolidated financial statements as of and for the nine months ended December 31, 2003 have been translated from Japanese yen amounts at the rate of ¥107 to U.S.\$1.00, the exchange rate prevailing on December 31, 2003. This translation is presented for convenience only and should not be construed as a representation that Japanese yen have been, could have been, or could in the future be, converted into U.S. dollars at that or any other rate.

#### 4. Inventories

Inventories at December 31, 2003 and March 31, 2003 consisted of the following:

		М	illio	ns of yen	Thousands of U.S. dollars
	Dece	ember 31, 2003	M	farch 31, 2003	December 31, 2003
Finished products	¥	29,431	¥	18,616	\$ 275,056
Work in process and semifinished products		14,618		13,740	136,617
Raw materials and supplies		9,108		8,461	85,121
	¥	53,157	¥	40,817	\$ 496,794

#### 5. Depreciation

Depreciation of property, plant and equipment for the nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002 amounted to ¥9,239 million (\$86,346 thousand), ¥10,964 million and ¥11,359 million, respectively.

# 6. Short-term bank loans and long-term debt

The Company had no short-term bank loans as of December 31, 2003 or March 31, 2003.

Long-term debt at December 31, 2003 and March 31, 2003 consisted of the following:

		Millions of yen			Thousands of U.S. dollars
	Dece	ember 31, 2003	M	arch 31, 2003	December 31, 2003
1.05% unsecured convertible bonds due 2008	¥	3,438	¥	3,482	\$ 32,131
0.8969% unsecured bonds with warrants due 2008		6,312		6,312	58,991
- from banks due in installments through 2004 at 1.70%		9			84
- from banks due in installments through 2005 at rates ranging from 1.50% to 6.70%		_		303	
from 1.90% to 3.62%		1,002		_	9,364
from 1.90% to 3.62%				2,011	_
		10,761		12,108	100,570
Amounts due within one year		(11)		(140)	(103)
		10,750	¥	11,968	\$ 100,467

The conversion price and period of the convertible bonds are summarized as follows:

	Conversion price per share at December 31, 2003	Conversion period (up to and including)
1.05% unsecured convertible bonds due 2008	¥762.50	September 29, 2008

The warrants issued with the 0.8969% unsecured bonds due 2008 entitle the holders to subscribe for shares of common stock of the Company at ¥1,338.5108 per share from October 1, 2002 to September 29, 2008.

At December 31, 2003, if all outstanding convertible bonds had been converted at the then current conversion price, and all warrants had been exercised at the then current exercise price, 9.224.547 new shares would have been issuable.

Under the term of indentures, trust deeds and warrant agency agreements, the conversion and exercise prices are subject to adjustment in certain cases which include stock splits. Sufficient shares of common stock are reserved for the conversion of all outstanding convertible bonds and the exercise of all warrants.

The aggregate annual maturities of long-term debt subsequent to December 31, 2003 are summarized as follows:

Years ending December 31	Millions of yen	Thousands of U.S. dollars
2004 2005		\$ 103 9,346
2006	_	
2007	_	_
2008	9,750	91,121
	¥ 10,761	\$ 100,570

# 7. Shareholders' equity

On December 10, 2001, the Company and F. Hoffmann-La Roche Ltd. announced that they would enter into an alliance to create a leading research-driven Japanese pharmaceutical company to be formed by the merger of the Company (excluding Gen-Probe Holding Company Incorporated and Gen-Probe Incorporated) and Nippon Roche, a wholly owned subsidiary of Roche Pharmholding B.V. Roche Pharmholding B.V. agreed to make an additional cash contribution in order to raise its participation to 50.1% of the agreed combined value. The alliance was approved by the shareholders of the Company at its annual general meeting held on June 27, 2002.

In accordance with terms of the alliance, the Company spunoff its wholly owned U.S. diagnostic business subsidiaries, Gen-Probe Holding Company Incorporated and Gen-Probe Incorporated, in September 2002. As a result, the common stock and additional paid-in capital accounts each decreased by ¥19,060 million. In addition, the Company issued 21,103,544 shares in September 2002 to Roche Pharmholding B.V. (the direct parent company) for ¥37,564 million and common stock and additional paid-in capital accounts each increased by ¥18,782 million. Furthermore, pursuant to the merger agreement between the Company and Roche Pharmholding B.V., the Company merged with Nippon Roche effective October 1,

2002. As a result, 196,628,960 shares were issued in October 2002 to Roche Pharmholding B.V. for ¥8,800 million which was credited to the additional paid-in capital account. At the same time as the merger with Nippon Roche, Roche Pharmholding B.V. exercised warrants which had been issued with the 0.8969% unsecured bonds due 2008 issued by Nippon Roche. In this connection, the common stock and additional paid-in capital accounts increased by ¥18,807 million and ¥18,765 million, respectively, and 28,069,610 shares were issued in October 1, 2002 to Roche Pharmholding B.V. As a

result, the equity participation of Roche Pharmholding B.V. in the Company was raised to approximately 50.1%.

The Code stipulates that an amount equal to at least 10% of the amounts to be disbursed as distributions of earnings be appropriated to the legal reserve until the legal reserve and additional paid-in capital equal 25% of the common stock account. The Code also stipulates that, to the extent that the sum of additional paid-in capital account and the legal reserve exceeds 25% of the common stock account, the amount of any such excess is available for appropriation by resolution of the shareholders.

# 8. Other income (expenses)

The components of "Other" in "Other income (expenses)" for the nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002 were as follows:

			Millions of yen			Thousands of U.S. dollars																
	Nine months ended December 31,		ended		ended		ended		ended		ended		ended		ended		ended		Years enc	led Marcl	n 31	Nine months ended December 31,
		2003	2003	20	002	2003																
Milestone payments made by Roche	. ¥	3,294	¥ —	¥	_	\$ 30,785																
Gain on disposition of land,																						
buildings and structures of a former Takada research laboratory	•	3,467	_		_	32,402																
Loss on disposition of equipment																						
and environmental recovery cost under termination activities		(2,777)			_	(25,953)																
Gain on sales of investment securities		1,313			_	12,271																
Integration costs (*)			(18,119)		_	_																
Written-off of long-term prepaid expenses		_	(3,882)		_																	
Gain on sales of distribution rights, etc.				3,	266	-																
Disposal costs and other expenses of inventories	ı	(131)	(247)	(1,	496)	(1,224)																
Loss on devaluation of investment securities			(1,703)	(3,	261)	_																
Other		1,146	_268		398	10,709																
	¥	6,312	¥ (23,683)	¥ (1,	093)	\$ 58,990																

<sup>(\*)</sup> Integration costs consisted of ¥13,444 million for the amortization of the unrecognized retirement benefit obligation under the prior retirement benefit plan and ¥4,675 million of consulting, IT integration and other expenses. Refer to Note 10 concerning the amortization of the unrecognized retirement benefit obligation under the prior plan.

#### 9. Income taxes

Income taxes in Japan applicable to the Company and its domestic subsidiaries consist of corporation tax, inhabitants' taxes, and enterprise tax. The approximate aggregate statutory tax rate was 41.5% for the nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002. Income taxes for the nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002 consisted of the following:

		Mil	Millions of yen		
_	Nine months ended December 31,	Years ende	d March 31	Nine months ended December 31,	
·	2003	2003	2002	2003	
Income taxes:					
Current	¥ 16,533	¥ 38,605	¥ 12,998	\$ 154,514	
Deferred	3,264	(12,126)	(1,325)	30,505	
	¥ 19,797	¥ 26,479	¥ 11,673	\$ 185,019	

Income taxes for the year ended March 31, 2003 include ¥22,384 million of taxes resulting from a taxable gain on the transfer of the Company's investment in Gen-Probe Incorporated ("Gen-Probe") following its spin-off. Refer to Note 7 with respect to the spin-off of Gen-Probe.

The significant components of deferred tax assets and liabilities at December 31, 2003 and March 31, 2003 were as follows:

		Mi	illior	is of yen		sands of . dollars
	Dece	ember 31, 2003	М	arch 31, 2003	Dece	mber 31, 2003
Deferred tax assets:						
Reserve for employees' retirement benefits	¥	14,584	¥	15,199	\$ :	136,299
Amortization of deferred charges		5,569		3,506		52,047
Enterprise tax payable		1		2,796		9
Prepaid expenses		2,182		2,079		20,393
Reserve for bonuses to employees		1,748		2,762		16,336
Other		8,993		9,675		84,047
Subtotal		33,077		36,017	:	309,131
Amounts offset by deferred tax liabilities		(2,766)		(1,588)		(25,850)
Deferred tax assets, net		30,311	¥	34,429	\$ 2	283,281
Deferred tax liabilities:						
Unrealized gain on securities	¥	1,536	¥	680	\$	14,355
Deferred gain on sales of properties for tax purposes		854		919		7,981
Other		398		13		3,719
Subtotal		2,788		1,612		26,055
Amounts offset by deferred tax assets		(2,766)		(1,588)		(25,850)
Deferred tax liabilities		22	¥	24	\$	205

Disclosure of the reconciliation of the statutory and effective tax rates for the nine months ended December 2003 has been omitted as the difference between the statutory tax rate of 41.5% and the effective tax rate of 40.2% was insignificant.

A reconciliation of the statutory tax rate and the effective tax rates for the years ended March 31, 2003 and 2002 is as follows:

	Years ended	March 31
	2003	2002
Statutory tax rate	41.5%	41.5%
Permanently non-deductible expenses for tax purposes such as entertainment expenses	21.3	5.4
Permanently non-taxable income such as dividend income	(3.4)	(0.2)
Inhabitants' per capita taxes	1.5	0.4
Different tax rates applied for overseas subsidiaries	(5.6)	(0.5)
Tax benefits of research and development costs	(12.9)	(2.4)
Gain on transfer of investment in Gen-Probe for tax purposes	326.3	_
Effect of tax rate change	15.0	_
Other	2.3	0.2
Effective tax rates	386.0%	44.4%

The aggregate statutory tax rate will change from 41.5% to 39.5% effective the fiscal year beginning after March 31, 2004 in accordance with a revision of income tax regulation in March 2003. The effect of this tax rate change was to decrease deferred tax assets by ¥998 million and to increase income taxes – deferred by ¥1,031 million for the year ended March 31, 2003.

#### 10. Retirement benefits

# (a) Overview of retirement benefits

The Company has various defined benefit plans such as a welfare pension fund plan, a tax qualified pension plan and a lump-sum payment plan. Additional retirement benefits may, in certain cases, be paid to employees upon retirement. The Company's domestic consolidated subsidiaries participate in the lump-sum payment plan.

As a result of the Company's merger with Nippon Roche effective October 1, 2002, the number of employees increased significantly and this resulted in the termination of the

Company's prior retirement benefit plans and the implementation of new retirement benefit plans. In this connection, the Company has charged or credited all of unrecognized balances, as of September 30, 2002, which consisted principally of ¥9,813 million of unrecognized actuarial loss and ¥1,401 million of unrecognized prior service cost (as credited) at September 30, 2002, and ¥25 million of prior service cost (as credited) under the new employees' retirement benefit plan effective October 1, 2002, as well as ¥5,057 million of actuarial loss due to a change in the discount rate from 3.0% under the prior plan, to 2.5%.

# (b) Retirement benefit obligation

	М	illions of yen	Thousands of U.S. dollars
	December 31, 2003	March 31, 2003	December 31, 2003
Retirement benefit obligation	¥ (90,916)	¥ (83,642)	\$ (849,682)
Plan assets at fair value	50,527	41,204	472,215
Unfunded retirement benefit obligation	(40,389)	(42,438)	(377,467)
Unrecognized prior service cost		(755)	(5,972)
Unrecognized actuarial loss	1,470	884	13,738
Reserve for employees' retirement benefits	¥ (39,558)	¥ (42,309)	\$ (369,701)

The government-sponsored portion of the Welfare Pension Fund Plan is included in the amounts presented.

# (c) Retirement benefit expenses

				М	sands of dollars		
		months ended nber 31,	Years ended March 31			months ended nber 31,	
		2003		2003		2002	 2003
Service cost (*)	¥	3,074	¥	3,934	¥	3,229	\$ 28,729
Interest expense		1,558		1,937		1,785	14,561
Expected return on pension plan assets		(618)		(679)		(638)	(5,776)
Amortization of unrecognized retirement benefit obligation under the prior plan		_		13,444		_	_
Amortization of actuarial loss		137		742		1,562	1,280
Amortization of prior service cost		(117)		(248)		(405)	(1,093)
Additional retirement benefits paid		11		1,167		268	103
Total retirement benefit expenses		4,045	¥	20,297	¥	5,801	\$ 37,804

 $<sup>(\</sup>star)$ The participants' contributions to the Welfare Pension Fund Plan have been deducted from the amounts presented.

# (d) The assumptions and policies adopted in accounting for the retirement benefit plans are summarized as follows:

	Nine months ended December 31,	Years ended N	March 31
	2003	2003	2002
1) Discount rates:	2.0% (at the beginning of the current fiscal year, the rate applied was 2.5%)	2.5% (at the beginning of the current fiscal year, the rate applied was 3.0%)	3.0%
2) Expected rate of return on plan assets:	2.0%	2.0%	2.0%

(Regarding the life insurance company's portion of the retirement benefit plan assets, the rate of return guaranteed at the time of the signing of the contract was approximately 5.5% and this rate has been included in calculating the overall expected rate of return on the retirement benefit plan assets.)

#### 11. Leases

The Company holds certain machinery and equipment under finance leases which do not transfer the ownership to the lessee. These leases are not capitalized, but are accounted for as operating leases. If the leases had been capitalized, the acquisition costs, accumulated depreciation and net book value of the leased assets at December 31, 2003 and March 31, 2003 would have been as follows:

										Decemb	er 3	1, 2003
				M	lillion	ns of yen			Τŀ	nousands o	f U.	S. dollars
	Mac	hinery	Eq	uipment		Total	Ma	chinery	Ec	quipment		Total
Acquisition costs	¥	62	¥	2,020	¥	2,082	\$	579	\$	18,879	\$	19,467
Accumulated depreciation		29		1,203		1,233		271		11,243		11,523
Net book value	¥	33	¥	817	¥	850	\$	308	\$	7,636	\$	7,944

				Mar	ch 3	1, 2003
				М	illion	s of yen
	Machinery		Equipment			Total
Acquisition costs	¥	38	¥	2,377	¥	2,415
Accumulated depreciation		22		1,377		1,399
Net book value	¥	16	¥	1,000	¥	1,016

Rental expenses, primarily for office space and equipment, amounted to ¥4,514 million (\$42,187 thousand), ¥5,783 million and ¥5,059 million for the nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002, respectively.

Lease payments relating to finance leases accounted for as operating leases included in the above figures totaled ¥320 million (\$2,991 thousand), ¥464 million and ¥525 million for the

Years ending December 31	Million	s of yen	sands of . dollars
2004	¥	369	\$ 3,449
2005 and thereafter		481	4,495
	¥	850	\$ 7,944

nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002, respectively, which are equal to the depreciation expense of the leased assets computed by the straight-line method over the respective lease terms. Future minimum lease payments subsequent to December 31, 2003 for finance leases accounted for as operating leases are summarized as follows:

#### 12. Securities

Securities consisted of marketable securities and non-marketable securities classified as other securities. The acquisition costs, carrying value and unrealized gain (loss) on marketable securities at December 31, 2003 and March 31, 2003 are summarized by type of security as follows:

#### 1. Other securities with determinable market value

		M	lillions of yen		Thousands o	f U.S. dollars
December 31, 2003	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
(1) Securities whose carrying value exceeds their acquisition cost:						
Stocks	¥ 4,367	¥ 8,265	¥ 3,898	\$ 40,813	\$ 77,243	\$ 36,430
Bonds	6,799	6,803	4	63,542	63,579	37
Subtotal	11,166	15,068	3,902	104,355	140,822	36,467
(2) Securities whose carrying value					-	
does not exceed their acquisition cost:						
Stocks	114	95	(19)	1,065	888	(177)
Bonds	32,000	31,991	(9)	299,066	298,981	(85)
Subtotal	32,114	32,086	(28)	300,131	299,869	(262)
Total	¥ 43,280	¥ 47,154	¥ 3,874	\$ 404,486	\$ 440,691	\$ 36,205

		М	illions of yen
March 31, 2003	Acquisition cost	Carrying value	Unrealized gain (loss)
(1) Securities whose carrying value exceeds their acquisition cost:			
Stocks	¥ 2,846	¥ 5,236	¥ 2,390
Bonds	5,000	5,007	7
Other	7,999	7,999	0
Subtotal	15,845	18,242	2,397
(2) Securities whose carrying value			
does not exceed their acquisition cost:			
Stocks	2,972	2,369	(603)
Bonds	39,200	39,115	(85)
Other	7,499	7,499	(0)
Subtotal	49,671	48,983	(688)
Total	¥ 65,516	¥ 67,225	¥ 1,709

# 2. Sales of securities classified as other securities

The sales and aggregate gain and loss on sales of securities classified as other securities for the nine months ended December 31, 2003 and the year ended March 31, 2003 are summarized as follows:

		N	lillior	ns of yen	 sands of . dollars
	Nine months ended December 31,		Yea	ar ended	
		2003		2003	 2003
Sales proceeds	¥	5,304	¥	4,535	\$ 49,570
Gain		1,313		1,792	12,271
Loss		(26)		(1,256)	 (243)

For the year ended March 31, 2002 there were no sales of securities classified as other securities.

# 3. Securities without determinable market value

		M	lillion	s of yen		sands of . dollars
	Decer	nber 31, 2003	Ma	arch 31, 2003	Dece	mber 31, 2003
Other securities: Unlisted securities, except for those traded on the OTC market and other	. ¥	583	¥	644	\$	5,449

# 4. The schedule for redemption of other securities with maturity dates is summarized as follows:

_		Millions of yer	Thous	ands of U.S. dollars
December 31, 2003	Due in one year or less	Due after one yea through five year	Due in one year or less	Due after one year through five years
Other securities with maturity dates:	*			
Corporate bonds	¥ 18,695	¥ 8,10	\$ 174,720	\$ 75,701
Other	12,000	_	- 112,149	
Total	¥ 30,695	¥ 8,10	\$ 286,869	\$ 75,701

		Millions of yen
March 31, 2003	Due in one year or less	Due after one year through five years
Other securities with maturity dates:		
Corporate bonds	¥ 31,787	¥ 12,336
Other	15,498	
Total	¥ 47,285	¥ 12,336

#### 13. Derivatives

The Company utilizes derivative financial instruments such as forward foreign exchange contracts, currency swaps and interest-rate swaps for the purpose of hedging its market risk, but does not enter into such transactions for speculative trading purposes.

The Company is exposed to certain market risk arising from the forward foreign exchange contracts and swap agreements referred to above. The Company is also exposed to the risk of a credit loss in the event of non-performance by its counterparties to these derivatives positions; however, the Company does not anticipate non-performance by any of the counterparties, all of whom are financial institutions with high credit ratings.

The Company enters into these derivatives transactions in accordance with the policies and strategies established by management. Routine operations involving derivatives transactions are subject to strict oversight by management.

The contract amounts of the financial derivatives in the following tables are nominal amounts or notional principal amounts and thus do not fully reflect the potential risk associated with these derivatives positions.

Summarized below are the notional amounts and the estimated fair value of the open derivatives positions at December 31, 2003 and March 31, 2003:

# (1) Currency-related transactions

	-	Mi	llions of yen		T	housands of	of U.S. dollars		
December 31, 2003  Forward foreign exchange contracts	Notional amounts	Fair value	Ur	nrealized gain	Notional amounts	Fair value	Unr	ealized gain	
Forward foreign exchange contracts									
Buy:									
Swiss francs	¥ 14,008	¥ 14,561	¥	554	\$130,915	\$136,084	\$	5,178	
Sell:									
Euro	945	922		23	8,832	8,617		215	
Currency swaps:									
Euro/yen	1,000	64		64	9,346	598		598	
Total			¥	641			\$	5,991	

				Mil	lions	of yen	
March 31, 2003		Notional amounts Fa		Fair value		Unrealized gain	
Forward foreign exchange contracts							
Buy:		0.650		^ <b>/5</b> /			
Swiss francs	¥	9,659	¥	9,6/4	¥	15	
Currency swaps:							
Euro/yen		1,000		94		94	
Total					¥	109	

#### (2) Interest-related transactions

			Millions of yen				Thousands of U.S. dollar					dollars
December 31, 2003	_	lotional mounts	Fa	ir value		realized in (loss)	_	otional nounts	Fa	ir value		realized in (loss)
Interest-rate swaps:												
Receive/floating and pay/fixed	¥	5,000	¥	(404)	¥	(404)	\$	46,729	\$	(3,776)	\$	(3,776)
Receive/fixed and pay/floating		5,000		415		415		46,729		3,879		3,879
Total					¥	11					\$	103

				М	illi	ons of yen
March 31, 2003		Notional amounts		Fair value		Unrealized gain (loss)
Interest-rate swaps:		-				
Receive/floating and pay/fixed	¥	5,000	¥	(490)	¥	(490)
Receive/fixed and pay/floating		6,000		605		605
Total					¥	115

# Notes to Consolidated Financial Statements

#### 14. Segment information

The Company and its consolidated subsidiaries are engaged principally in the manufacture and sales of pharmaceutical products in Japan and overseas.

#### Business segments

As net sales, operating income and total assets of the nonpharmaceutical segments constituted less than 10% of the consolidated totals for the nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002, the disclosure of business segment information has been omitted.

# Geographical segments

As net sales and total assets of the overseas consolidated subsidiaries constituted less than 10% of the consolidated totals for the nine months ended December 31, 2003, and the years ended March 31, 2003 and 2002, the disclosure of geographical segment information has been omitted.

#### Overseas sales

As overseas sales constituted less than 10% of the consolidated sales for nine months ended December 31, 2003 and the year ended March 31, 2003, the disclosure of overseas sales information has been omitted.

Effective the year ended March 31, 2003, the Company changed its accounting for royalties. The effect of this change was to decrease overseas sales by ¥364 million, which resulted in overseas sales totaling ¥15,448 million, or 6.5% of consolidated net sales, for the year ended March 31, 2003.

Overseas sales, which include export sales of the Company and sales of its overseas consolidated subsidiaries (other than sales to Japan), for the year ended March 31, 2002 are summarized as follows:

		_	_		M	lillions of yen
Year ended March 31, 2002	No Amei		Europe		Other	Total
Overseas sales  Consolidated net sales  Overseas sales as a percentage	¥ 15,38	86 ¥	11,895	¥	1,831	¥ 29,112 211,705
of consolidated net sales	7	'.3%	5.6%	)	0.9%	13.8%

# 15. Contingent liabilities

At December 31, 2003 and March 31, 2003, the Company was contingently liable as guarantor of loan obligations of ¥1,276 million (\$11,925 thousand) and ¥1,457 million in the aggregate, respectively, for its employees.

#### 16. Supplementary cash flow information

(1) Summary of assets and liabilities of companies excluded from consolidation due to the spin-off of certain U.S. subsidiaries The following is a summary of the transferred assets and liabilities which affected the consolidated statements of cash flow for the year ended March 31, 2003:

# Gen-Probe Holding Company Incorporated (at December 31, 2001)

	Millio	ns of yen
Current assets	. ¥	1,085
Non-current assets		16,718
Total assets		17,803
Current liabilities	. ¥	0
Total liabilities	. ¥	0

# Gen-Probe Incorporated (at December 31, 2001)

	Million	ns of yen
Current assets	. ¥	7,499
Non-current assets		13,659
Total assets		21,158
Current liabilities	. ¥	3,572
Non-current liabilities		2,305
Total liabilities	¥	5,877

# (2) Significant non-cash transactions

# (a) Convertible bonds and warrants

				N	fillion	ns of yen		sands of dollars
	Nine months ended December 31,							months ended ber 31,
		2003	:	2003		2002	_	2003
Decrease in convertible bonds resulting from conversion		43	¥ 51	1,261 7,571	¥	82	\$	402

# (b) Acquisition of assets and liabilities from Nippon Roche effective October 1, 2002, the date of the merger

The following is a summary of the acquired assets and liabilities which affected the consolidated statements of cash flow for the year ended March 31, 2003:

At October 1, 2002	Millions of yen					
Current assets	¥ 61,158					
Non-current assets	19,714					
Total assets	¥ 80,872					
Current liabilities	¥ 7,890					
Non-current liabilities	52,729					
Total liabilities	¥ 60,619					
Additional paid-in capital	¥ 8,800					

#### 17. Related party transactions

The Company is substantively a 50.5%-owned consolidated subsidiary of Roche Pharmholding B.V. (the parent company). The parent company is indirectly owned by Roche Holding Ltd. (Roche Holding). The Company principally purchases raw materials from F. Hoffmann-La Roche Ltd. (Roche), a consolidated subsidiary of Roche Holding.

Significant balances at December 31, 2003 and March 31, 2003 and transactions for the nine months ended December 31, 2003 and the year ended March 31, 2003 with related parties are summarized as follows:

		М	illion	s of yen		usands of S. dollars
	Dec	ember 31, 2003	M	arch 31, 2003	Dec	ember 31, 2003
Balances:						
The parent company:						
Bonds						
with warrants	¥	6,312	¥	6,312	\$	58,991
Other payables		14		28		131
Roche:						
Trade payables		10,827		9,174		101,187

		Millions of yen	Thousands of U.S. dollars
	Nine months ended December 31,	Year ended March 31,	Nine months ended December 31,
Transactions:	2003	2003	2003
The parent company: Interest expense			
on bonds	¥ 43	¥ 28	\$ 402
Roche: Purchases of			
raw materials	35,523	21,623	331,991

# 18. Amounts per share

Basic net income per share is computed based on the net income available for distribution to shareholders of common stock and the weighted average number of shares of common stock outstanding during each year, and diluted net income per share is computed based on the net income available for distribution to the shareholders and the weighted average number of shares of common stock outstanding each year after giving effect to the dilutive potential of common shares of common stock to be issued upon the conversion of convertible bonds, exercise of warrants and stock option.

Diluted net loss per share for the year ended March 31, 2003 has not been presented because the effect of the conversion of the convertible bonds would have had an anti-dilutive effect on the computation of net loss per share.

Net assets per share are based on the number of shares of common stock outstanding at each balance sheet date.

	Nine months ended December 31,		Yen Years ended March 31		U.S. dollars  Nine months ended December 31,	
	2003	2003	2002	_	2003	
Net income (loss):						
Basic	. ¥	51.73	¥ (51.75)	¥ 57.93	\$	0.48
Diluted		50.94		49.09		0.48
	_			Yen	U.S	. dollar
			December 31, 2003	March 31, 2003	Dece	mber 31 2003

The dilutive potential of 9,256,440 shares of common stock from the 1.05% unsecured convertible bonds due 2008 and the warrants issued with the 0.8969% unsecured bonds due 2008 has been included in the computation of the weighted average number of shares of common stock outstanding.

Net assets .....

In addition, non-dilutive potential of 231,000 shares of common stock to be issued under the Company's stock option plans, which has not been included in the computation of the weighted average number of shares of common stock outstanding, also remained outstanding at December 31, 2003. The stock option plan entitle the directors and certain key employees of the Company and its subsidiaries to exercise warrants which were approved at a general meeting of the shareholders held on June 25, 2003 in accordance with Articles 280-20 and 280-21 of the Commercial Code. Under the plan, 231,000 shares of common stock are issuable at an exercise price of ¥1,454 (\$13.59) per share as of December 31, 2003.

# 19. Subsequent event

The following appropriations of retained earnings, which have not been reflected in the accompanying consolidated financial statements for the nine months ended December 31, 2003, were approved at a general meeting of the shareholders of the Company held on March 25, 2004:

	Millions of yen		Thousands of U.S. dollars		
Cash dividends	. ¥	7,102	\$ 66,374		
corporate auditors		90	841		

542.96

503.41

5.07

■ Certified Public Accountants Hibiya Kokusai Bldg. 2-2-3. Uchisaiwai-cho Chiyoda-ku, Tokyo 100-0011 C.P.O. Box 1196, Tokyo 100-8641 Phone: 03 3503-1191 Fax: 03 3503-1277

# Report of Independent Auditors

The Board of Directors Chugai Pharmaceutical Co., Ltd.

We have audited the accompanying consolidated balance sheets of Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries as of December 31, 2003 and March 31, 2003 and the related consolidated statements of operations, shareholders' equity, and cash flows for the nine months ended December 31, 2003 and each of the two years in the period ended March 31, 2003, all expressed in yen. These financial statements are the responsibility of the Company's management. Our responsibility is to independently express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards, procedures and practices generally accepted and applied in Japan. Those standards, procedures and practices require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries at December 31, 2003 and March 31, 2003, and the consolidated results of their operations and their cash flows for the nine months ended December 31, 2003 and each of the two years in the period ended March 31, 2003 in conformity with accounting principles and practices generally accepted in Japan.

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the nine months ended December 31, 2003 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 3 to the consolidated financial statements.

Thin Milen & Co.

March 25, 2004

See Note 1 to the consolidated financial statements which explains the basis of preparation of the consolidated financial statements of Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries under Japanese accounting principles and practices.

#### Head office

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#### **Branches**

Sapporo, Sendai, Tokyo 1, Tokyo 2, Yokohama, Kanshinetsu, Nagoya, Osaka, Kyoto, Kobe, Takamatsu, Hiroshima, Fukuoka

#### **Plants**

Ukima (Tokyo), Kagamiishi (Fukushima), Fujieda (Shizuoka), Utsunomiya (Tochigi), Kamakura (Kanagawa)

## Research laboratories

Fuji Gotemba (Shizuoka), Tsukuba (Ibaraki), Kamakura (Kanagawa), Ukima (Tokyo)

#### Domestic subsidiaries

Eiko Kasei Co., Ltd.
Chugai Research Institute
for Medical Science, Inc.
Chugai Business Support Co., Ltd.
Medical Culture Inc.
Chugai Distribution Co., Ltd.
Chugai Techno Business Co., Ltd.
Tohoku Chugai Pharmaceutical Co., Ltd.

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Guangzhou 510060, China Telephone: +86-(0) 20-8363-4399

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Chugai Pharma Marketing Ltd.

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#### C&C Research Laboratories\*

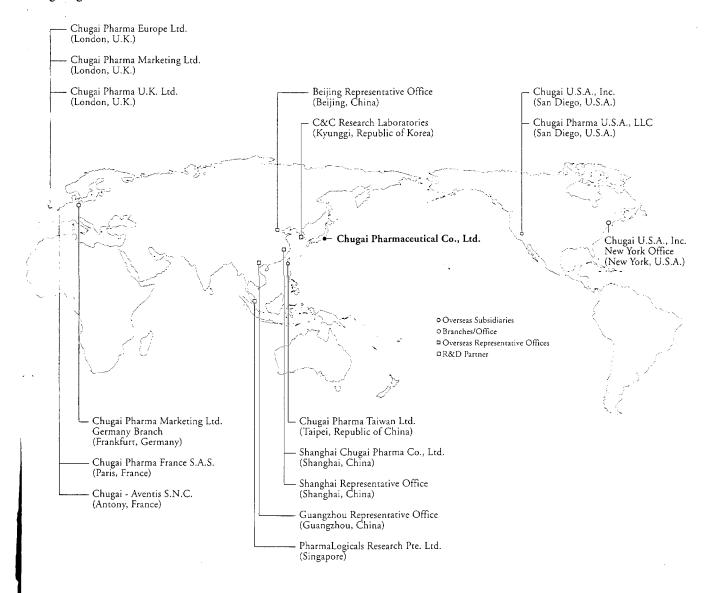
146-141, Annyung-ri, Taean-up

Hwasung-si, Kyunggi-do 445-970 Republic of Korea

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\* Affiliate

# Chugai's global network



# Chugai Pharmaceutical Co., Ltd.

Year of Foundation:

1925

Stated Capital:

¥ 68,237,416,055

Number of Shares Issued of

Common Stock:

550,691,219

Number of Shareholders:

23,063

Stock Listing:

Tokyo

Fiscal Year-End:

December 31\*

General Meeting of Shareholders: March

Stock Transfer Agent:

UFJ Trust Bank Limited

Newspaper for Public Notices:

Nihon Keizai Shimbun

(As of December 31, 2003)

# Major Shareholders (Top10)

Name	Number of Shares Held (Thousands)	Percentage of Ownership Voting (%)
Roche Pharmholding B.V.	275,802	50.52
Street Bank And Trust Company	25,553	4.68
The Master Trust Bank of Japan, Ltd., trust account	22,870	4.19
The Chase Manhattan Bank, N.A., London	18,644	3.42
Japan Trustee Services Bank, Ltd. trust account	16,498	3.02
The Chase Manhattan Bank, N.A., London, Secs Lending Omnibus Account	15,887	2.91
J.P. Morgan Trust Bank, Ltd. tax-free account	9,080	1.66
The Nichido Fire and Marine Insurance Co., Ltd	l. 5,767	1.06
Investors Bank and Trust Company (west)-Trea	aty 5,193	0.95
JPM Chase Oppenheimer Funds JASDEC A/C	3,917	0.72

<sup>4,376,622</sup> shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

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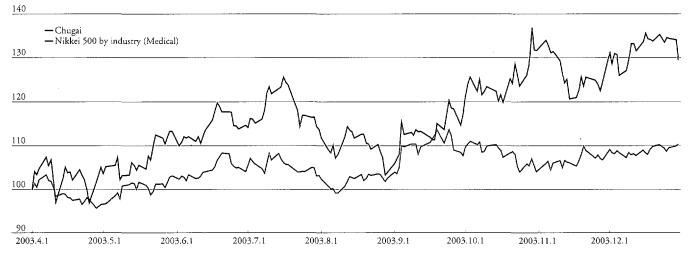
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#### Stock Price Information

	Stock Price		
	High	Low	
From April 1, 2003 to December 31, 2003			
Second Quarter	¥ 1,454	¥ 1,152	
Third Quarter	1,509	1,212	
Fourth Quarter	1,635	1,407	

# Share Performance of Chugai



Share price on April 1, 2003 (¥1,190) = 100

<sup>\*</sup>Fiscal year-end has been changed to December 31 since the fiscal year started April 1, 2003.

